REPORT ON THE PCB INCIDENT IN THE WESTERN UNITED STATES

FOOD SAFETY AND QUALITY SERVICE
UNITED STATES DEPARTMENT
OF AGRICULTURE

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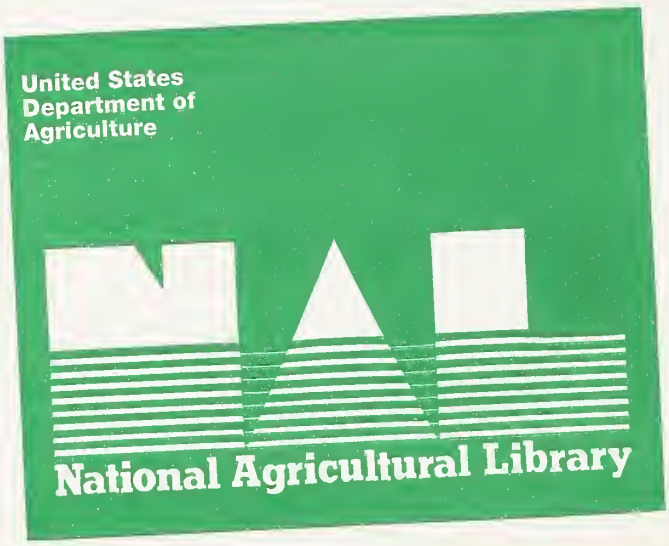
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I. SCOPE AND PURPOSE

The discovery and cleanup of a recent polychlorinated biphenyl (PCB) spill in the Western United States has triggered a reexamination of USDA policy in the areas of residues and environmental contaminants. The handling of the problem in USDA and the rest of the public sector revealed a number of problems that involve both administrative procedures and fundamental sensitivity toward a new class of problems. While still in the midst of struggling with the cleanup of PCB contaminated goods, this report attempts to analyse and evaluate the initial USDA response and describes changes that must be implemented if the Federal government is to be more effective. This is no academic exercise; the prevalence of toxic chemicals in our environment ensures that accidents will happen that test the capacity of government to respond flexibly and effectively. This paper uses the PCB incident as a case study to design workable policies and procedures that create a sense of urgency while guaranteeing a measured and systematic response.

In writing the report, the Food Safety and Quality Service has attempted the difficult task of self-examination. For such an endeavor to be successful, it must avoid the natural human tendency to justify mistakes and gloss over weaknesses. The report, therefore, concentrates more on the Agency's weaknesses than on its strengths. The Agency believes that one measure of its strength is the ability to view itself critically. The report is not intended as a mea culpa. The

record shows that it was FSQS that discovered the contamination and then, in cooperation with other agencies, took a series of actions that kept large amounts of contaminated food from reaching consumers. The cause of the contamination in the first place was an industrial accident, and was in no way due to any negligence or dereliction on the part of any governmental agency. As Representative Albert Gore, Jr., pointed out at the September 28 hearing, "It wasn't the government that put this stuff in the environment." FSQS, however, recognizes its responsibility to help do something about the problem. As Representative Gore stated, "The only solution to (the) problem is for us Americans working through our government to enact regulations to prevent the abuses of these new substances."

The report will proceed as follows: Part II provides background material on the nature of PCBs, the legal responsibilities for regulating PCBs, and a brief history of the USDA National Residue Program. Part III presents a detailed account of the recent incident. It is both a chronology and an analysis of what went right and what went wrong. Problems are highlighted, and possible solutions suggested. This part is based on an intensive review of the agency's performance in discovering and responding to the contamination.

Part IV of this report takes the material and problems developed in the previous section and begins constructing solutions. Some actions have already been taken by USDA and these are presented. After a discussion of the direction of the current program and alternative

objectives, a variety of solutions and problems of implementation are arrayed. Prudent policy must proceed on several different levels. The following broad initiatives will be considered: (1) educational and public information tools to communicate the importance of the problem to the public and to our own employees; (2) procedural directives designed to translate policy into routine action and ensure proper coordination of response to emergencies; (3) regulatory action designed to limit the potential danger from industrial chemicals, and encourage industry to take increased responsibility for their actions; (4) new legislation to ensure that USDA has the authority necessary to contain and control problems; and (5) budget and policy approaches to ensure that USDA's National Residue Monitoring System is properly focused.

II. BACKGROUND AND HISTORY

A. What Are PCBs?

Polychlorinated biphenyls (PCBs) are part of a broad group of organic chemicals known as chlorinated hydrocarbons. Research into the effects of exposure to PCBs has yielded data indicating that these substances can cause health disorders including reproductive failures, gastric disorders, skin lesions, and tumors in laboratory animals. Studies of human exposure to PCBs at levels much higher than those encountered in the recent incident have indicated a high incidence of skin disorders, digestive disturbances, jaundice, throat and respiratory irritations, and severe headaches. These chemicals were produced in the United States, primarily by the Monsanto Corporation, from 1929 to 1977 and were primarily used in closed systems in electrical transformers, capacitators, heat transfer systems and hydraulic systems. When they were legally marketed, PCBs were commercially attractive due to their high degree of chemical stability, low solubility in water, low vapor pressure, low flammability, high heat capacity and low electrical conductivity.

B. Regulation of PCBs

1. Environmental Protection Agency

The Toxic Substances Control Act (15 U.S.C. 2601 et seq.) requires the Environmental Protection Agency (EPA) to control the manufacture, processing, distribution in commerce, use, disposal, and marking of PCBs. Section 6(e)(3) provides that no person may manufacture any PCB after January 1, 1979, or process or distribute in commerce any PCB after July 1, 1979, except to the extent that EPA specifically exempts such activity. Implementation of the January 1, 1979, ban was subsequently postponed until 30 days after completion of EPA rulemaking on May 31, 1979 (44 FR 31514). Specifically, the May 31 rule: (1) prohibits all manufacturing of PCBs after July 2, 1979, unless it is specifically exempted by EPA; (2) prohibits the processing, distribution in commerce, and use of PCBs except in a totally enclosed manner after July 2, 1979; and (3) defines the exemptions which would authorize certain processing, distribution in commerce, and use of PCBs in a nontotally enclosed manner which would otherwise be subject to the prohibition.

2. Food and Drug Administration

The Food and Drug Administration (FDA) regulates PCBs in the food supply under the authority of the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). In issuing regulations in this area, FDA has

classified PCBs as "unavoidable contaminants" of food. Under Section 402, food is considered adulterated and thus prohibited from distribution in commerce if it contains any added poisonous or added deleterious substance that is unsafe within the meaning of Section 406. This latter provision deems any such substance to be unsafe unless its presence in food is required in the production thereof, or cannot be avoided by good manufacturing practice.

Section 406 also authorizes FDA to promulgate regulations limiting the quantity of such a required or unavoidable substance that can be legally present in food. FDA has recognized that the toxicological data available on PCBs makes it clear that under ideal circumstances it would be preferable not to allow any levels of these substances in food. However, FDA's rulemaking in this area has also displayed a recognition of the former widespread use of these substances and of their highly persistent nature in the environment. Therefore the agency has established and periodically lowered the tolerances, codified at 21 CFR 109.30, for PCB in food as the substance has become less prevalent in the environment. These tolerances include a current level of 3 parts per million (ppm) in poultry and animals (fat basis) and .3 ppm in eggs. Foods which contain PCB residues in excess of these prescribed tolerances are deemed adulterated by FDA and their distribution in commerce is considered unlawful.

3. USDA Meat, Poultry and Egg Inspection

FSQS conducts inspection programs pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). Under the terms of these statutes, USDA has responsibilities for the control of chemical residues. Meat, poultry, and egg products are adulterared--and therefore prohibited for use as human food--if they contain unsafe levels of chemcial substances. Tolerance levels have been established for scores of different chemicals. These substances include pesticides, drugs, feed additives, as well as industrial chemicals such as PCBs that may be harmful to human health.

In the meat and poultry area, control of such substances is coordinated by the Residue Evaluation and Surveillance Division in the FSQS Science program. Procedures to be followed by FSQS personnel in this area are specified in MPI Directive 917.1 as supplemented by MPI Bulletin 77-114 (Attachments #1 and #2). The process which leads to the actual taking of samples in federally inspected facilities begins with the development of a yearly national residue program by staff scientists in Washington, D.C. These individuals analyze trends and attempt to allocate available resources in the most effective possible manner in order to require testing for substances of potential adverse health significance. The yearly plan is in turn modified as trends dictate on a monthly basis. The monthly plan specifies actual species to be tested, and actual substances to be tested for.

The approved monthly plan is programed into a computer which retains records of slaughter rates at all federally inspected meat and poultry establishments. On a random statistical basis, this computer prints out a monthly plan indicating which species are to be tested for which substances at which establishments. The computer also prints out individual forms (MP Form 23-1) for each test to be conducted, specifying all of this information. The monthly printouts and the individual MP 23-1 forms are then distributed throughout the meat and poultry inspection program through the appropriate regional and area offices. The forms themselves are then directed to the relevant establishments several weeks before a particular sample is to be taken. Samples are then transmitted to the appropriate regional laboratory for testing.

The responsibility for residue monitoring with the egg products inspection program is retained within the Poultry and Dairy Quality Division (PDQ), Commodity Services, FSQS. This program also identifies samples to be collected on a random computerized basis, designed to insure that egg products from each inspected facility are sampled on a quarterly basis. Each regional office is supplied with a printout identifying samples to be taken, and this information is transmitted to FSQS personnel in each inspected facility. All samples are forwarded to the PDQ laboratory in Gastonia, North Carolina for residue testing.

C. The National Residue Program: A Short History

USDA's National Residue Program was founded in 1967, but its origins can be found in two related historical trends that occurred in the period following the Second World War.

The first was the "toxics revolution" in American agriculture. The discovery following World War II that pesticides, like DDT, could be used to destroy certain insect pests of plants kindled the interest of agriculturalists in attacking other pest and disease problems with chemicals. Scientists and technologists responded to the problem with ingenuity, and developed a whole host of chemical solutions to farm problems. Not only DDT, but other hydrocarbons such as chlordane, heptachlor, dieldrin, and aldrin were introduced and used widely to combat pests. Drugs such as penicillin, streptomycin, tetracycline, and various sulfas were fed to animals to prevent disease and promote growth. As a result, American agriculture became dependent upon pesticides, drugs, and other chemicals to maintain high levels of production.

The second trend was the development of new analytical techniques capable of detecting low levels of chemical residues in food. In the late 1940's, the techniques for detecting residues in food were quite rudimentary. At the Department of Agriculture, for example, technologists would place a piece of meat in water, along with a mosquito larva. If the larva died, then it was considered likely that

residues of DDT or some other potentially dangerous chemicals were present in the meat. In the late 1950's, sophisticated new analytical techniques, such as gas chromatography and spectrometry, came into use. These techniques enabled government scientists to detect chemical residues at progressively lower levels, and to determine more readily the exact chemical or chemicals present.

Because of the new analytical techniques, the full consequences of the "toxics revolution" began to be known. Scientists found that dangerous chemicals had become ubiquitous in our environment: in the air we breathe, the water we drink, and the food we eat. They resulted not only from agriculture use, but from the widespread industrial use of new chemicals. Rising public alarm (Rachel Carson's Silent Spring was one notable example) led to a series of government actions to control toxic chemicals. The founding of USDA's National Residue Program in 1967 was one of these actions. The Department previously had tested for chemicals in meat and poultry, but not on a systematic, nationwide basis. Before 1967, for example, the Department may have tested for the presence of lead when an inspector had noticed a staggering steer in a slaughterhouse pen; the inspector knew the steer may have licked some paint from a fence. But there was no systematic sampling in the absence of overt signs of contamination.

While it represented an important step forward when it began years ago, the National Residue Program was at first a rather modest undertaking. During the first year, approximately 1,000 tests were

run on meat and poultry samples. About 700 of the tests were for antibiotics, and the remainder were mostly for hydrocarbons (such as DDT) and trace elements (such as mercury or lead). The budget during that period was about $100,000/year, and there were only two people in Washington associated directly with the residue program on a full-time basis.

The Residue Program expanded largely in response to increased evidence of new and varied sources of food contamination. Scientists first became aware of the dangers of PCB contamination, for example, as a result of an incident in Yusho, Japan, in 1968. In the Yusho incident, a heat exchanger leaked PCB into rice oil, which later was consumed by Japanese families. Approximately 1,000 people were eventually affected. Typical clinical findings included chloracne (skin eruptions) and increased pigmentation, visual impairment, systematic gastrointestinal symptoms that included abdominal pain and disturbance in liver function. A few babies were born with decreased birth weights and skin discoloration. Symptoms have been very persistent. One Japanese researcher has now reported an elevated incidence of liver cancer.

The residue program today has a budget of $4.5 million, and a staff of 50. In 1978, approximately 25,000 samples from meat and poultry were tested for the presence of 43 chemical residues. Despite this growth, the program still does not provide the coverage it should to adequately protect the American people from potentially dangerous chemicals. For

one thing, there are still significant technological barriers. Although the program tests for 43 chemicals, there are 100 other toxic chemicals that may be present in food, and for which there are no reliable methods of detection. The program is also limited by finite resources. FSQS cannot realistically test every carcass for residues. Some 120 million livestock and 3.5 billion poultry are inspected and marketed each year. The cost of testing all of them for residues would run about $100 billion a year.

For this reason, the present National Residue Program is based on a statistical sampling plan that provides a 95 percent assurance that if a violation rate of one percent or more exists in the national animal population, it will be detected over the course of a year. This plan leaves open the possibility that a significant but localized contamination incident will go undetected. In fact, it was only by chance (at rather long odds) that the recent PCB contamination was picked up on the National Monitoring Program. This has raised certain questions about the broad focus of the present sampling plan. Part IV of this report will explore some alternatives that may enable FSQS to catch more incidents and catch them sooner.

Within the present framework, FSQS is already taking steps to improve its residue program. A 1979 General Accounting Office report, and hearings by the Subcommittee on Oversight and Investigations, House Commerce Committee in 1978, have both emphasized the critical importance of improving the effort against residues. FSQS shares this

view. The fiscal year 1980 budget submitted by FSQS requests an additional $1,477,000 for laboratory services in order to enlarge its laboratory capabilities, expand the number and range of tests, increase the number of animals tested and speed up the reporting of results to animal producers. In addition, FSQS has developed and put into use a rapid test method for antibiotics that permits testing for certain residues in the slaughtering plants on the day of slaughter, and is working to develop other rapid screening tests.

Viewed in historical perspective, a salient fact emerges concerning the FSQS residue program: in most respects it is a relatively young program, and it is still developing. The future development of the residue program will depend upon continued public recognition of the critical nature of chemical residues in food, wise policy choices, and the imaginative application of new technology. The recent PCB incident in the Western United States provides some important lessons that will help guide such development.

III. THE PCB INCIDENT IN THE WESTERN UNITED STATES

A. Moving Toward Discovery: June to September 16, 1979

Chronologies are interesting for several reasons. At the most fundamental level, they permit us to see, as Monday Morning Quarterbacks, the actions of people as they attempt to struggle with problems. In the case of the recent PCB incident, they lend coherence to a disjointed series of events that often lacked a pattern during the time when the participants were immersed in events. One must always be careful not to impose a purely fictional pattern in hindsight. Handled properly, however, chronologies can be useful in apportioning praise and blame, and judging whether "systems" devised for routine activities can adapt to stressful situations. Chronologies can also be valuable as case studies, as models through which we learn how to cope with the future in a better way. The following chronology represents an attempt to construct a useful record and guide for future action, while avoiding the pitfall of false coherence.

At the September 28, 1979, hearing before the House Subcommittee on Oversight and Investigation, Interstate and Foreign Commerce Committee, USDA submitted a tentative chronology for the record. The reconstruction that follows here supplements that material, provides additional detail, and includes a brief analysis of the events. It serves as the official record of the incident. The events described in this section will serve as the basis for any individual actions that the

agency may take in the future to ensure that employees are fulfilling their responsibilities. Most importantly, however, it raises a number of questions about the adequacy of the current system, and provides clues about what a better system would look like.

June 1979.

Pierce Packing Company (Federal Establishment #691/P 2469) (Pierce), Billings, Montana, engages in meat slaughtering and processing under a grant of Federal inspection. Pierce also produces animal feed, which partially consists of inedible products rendered from animals it slaughters at the establishment. Prior to September 1979, a spare, unused electrical transformer was stored in a corner of the Pierce facility where inedible products were held before they were diverted into animal feed processing. In this area, hair from slaughtered animals was also collected and retained for pickup on a regular basis by an independent contractor.

Some time in June 1979, one of the fins on this transformer, which was larger but similar in design to the type of fin found on a home air-conditioning unit, was accidently broken. Pierce officials have speculated that this might have been caused by the impact of a back-loading tractor which was inside the facility for the purpose of picking up animal hair. At any rate the accident led to a rupture of the transformer's cooling system and a leakage of cooling fluids onto the floor in this inedible product area. These fluids, in turn, ran into

a drain pipe, along with various inedible substances, where they became mixed and processed into animal feed. The fluids which leaked from the transformer unit and into the animal feed contained PCBs. Pierce officials, who have stated they were unaware of the accident, unaware of the presence of PCBs within the transformer, and unaware of the health hazards associated with exposure to PCBs, marketed animal feed produced at this time in the normal fashion to its customers throughout the western United States. This included a shipment, made on June 25, of 50,450 pounds of bulk meat and bone meal to Ritewood Feed Mill, Franklin, Idaho.

The FSQS monthly sampling plan for July included the requirement that a fat sample be taken from a mature chicken at Jolly Wholesale Poultry, Provo, Utah, and transmitted to the Western Regional laboratory in San Francisco, California for testing for chlorinated hydrocarbon residues (including PCBs). MP Form 23-1 #213833 was printed which included this information. It was transmitted to the inspection office at Jolly Wholesale Poultry in mid-June.

July 1 - 13, 1979.

Jolly Wholesale Poultry (Federal Establishment #P 1313) is a federally inspected establishment which engages in the slaughter and processing of poultry in Provo, Utah. Inspection is ordinarily conducted under the supervision of Dr. William Boyer, a veterinarian.

Dr. Boyer is also responsible for two other federally inspected establishments in the area, and spends approximately one half of his working hours at the Jolly facility. A full-time line inspector is also assigned to the Jolly plant.

Dr. Boyer received requests for samples at one of the three plants every 4 to 6 weeks. He indicated that it is his normal procedure to place these requests in a particular desk drawer in his office and to assume a personal responsibility for the taking, preparation, and shipment of the sample.

Dr. Boyer began a 2-week vacation on July 1, 1979, and a relief veterinarian, Dr. Ronald Baker, assumed Dr. Boyer's responsibilities at Jolly. Dr. Baker indicated that he normally takes an inventory of the inspection office of the establishment where he is assigned in a relief capacity in order to check for special instructions and assignments such as the taking of residue monitoring samples. He did so upon arriving at Jolly on July 1, 1979, and discovered the specific form #213833.

On July 6, he recalls discussing the sample with Mr. Dan Brickerhoff, the full-time line inspector. After lunch, he stated that he left Jolly to carry out responsibilities at other establishments after agreeing that Mr. Brickerhoff would take the sample in his absence. Mr. Brickerhoff does not specifically recall these conversations, but does remember seeing form #213833 in the office that afternoon and deciding that he should take care of it. Mr. Brickerhoff also stated that he has had

little experience in the taking of such samples, which were normally done by his supervisory veterinarian.

Since the slaughtering operations for that day were completed, Mr. Brickerhoff obtained the sample from one of the barrels of fatty tissue set aside in the plant with other inedible products. He prepared the sample in what he felt was the ordinary fashion by filling out the 23-1 form (Attachment #3), although he did not specify the original owner of the poultry. He placed the sample and the form in the appropriate shipping container. Packaging and shipping instructions are diagrammed in Exhibit 3 of MPI Directive 917.1 (Attachment #1). Since the sample cannot be mailed immediately, but must be frozen at least overnight prior to shipment, Mr. Brickerhoff stored the shipping container in the plant's freezer compartment after packing it.

Dr. Baker and Mr. Brickerhoff resumed inspection in the Jolly plant during the week that began on July 9. However, they forgot about the sample in question, never discussed it, and did not notice it in the freezer. Mr. Brickerhoff stated that even on those rare occasions in the past when he had taken a sample, he had assumed no responsibility for its shipment. This again, was ordinarily taken care of by Dr. Boyer. Dr. Baker agreed the shipment of this particular sample and any other sample was within his own area of responsibility. Since the sample was not discovered, it remained in the freezer during the entire week of July 9-13 without being shipped.

July 16 - August 3.

Dr. Boyer returned to his regular assignment at Jolly on July 16. Dr. Baker and Mr. Brickerhoff were both routinely reassigned to other inspected establishments beginning on the same day. Dr. Boyer discovered the sample in the freezer late on the morning of July 16. He was in contact with representatives of the Boulder, Colorado area office which has supervisory responsibility in the State of Utah, discussing other items of business and mentioned the finding of the sample to his supervisor, Dr. Walter Huber, the area veterinarian in charge. Dr. Huber directed Dr. Boyer by all means to mail the sample as quickly as possible. The sample was mailed that day to the FSQS Western Laboratory in San Francisco, California.

The FSQS Western Laboratory is responsible for the majority of residue testing in the Western Region--which includes the States of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. It is directed by Dr. Paul H. Smith who supervises a staff of 39. Residue testing constitutes a significant part of the workload of the office, but is sometimes supplemented by special projects such as the testing of products to assist investigations by the FSQS Compliance staff.

The office receives from 30 to 50 residue samples per day. Pickups of samples are made from an office of the U.S. Postal Service, a few

blocks away from the laboratory in downtown San Francisco, at 7 a.m. and 1:30 p.m. each working day. In addition, the laboratory conducts pickups from the Post Office on weekends, in order to assure that samples remain frozen prior to being tested.

Upon arrival, samples are logged into the office, assigned a number, and placed in a freezer. Monitoring and surveillance samples are distinguished. Surveillance samples are those taken after a particular residue problem has been identified. As such, they are given priority treatment within the laboratory, and every attempt is made to complete the necessary analytical procedures within 3 working days of receipt. Monitoring samples, on the other hand, are considered routine. Laboratory personnel have no indication this type of sample may be violative until it is tested. As a result, the office's ability to process monitoring samples expeditiously is a function of its workload in the surveillance area. All efforts are made to conduct routine monitoring tests within 14 calendar days of receipt. This is consistent with established FSQS policy, as specified by Dr. Ronald E. Engel, Deputy Administrator for Science, in a number of memoranda, the most recent being that of September 21, 1978, (Attachment #4).

The fat sample mailed by Dr. Boyer from Jolly on July 16 arrived at the laboratory on July 20 and was processed in the normal manner. It was appropriately classified as a routine monitoring sample and was retained in a laboratory freezer until being prepared for analysis on July 24. Routine testing began on July 25. The testing was assigned to Michael Wong, Staff Chemist.

Sample #213833 was initially tested with nine other samples grouped together before being subjected to what is referred to as the Alumina screening procedure. Fatty substances are rendered away from the product, which is then processed through a solvent designed to separate residues from other substances. This solvent extract is then concentrated. At this point, a portion of the remaining solution is then injected into a machine known as a gas chromatograph. Samples from all of the substances being tested were injected into such a machine by Mr. Wong on July 27.

The machine reacts to each substance being tested by printing a pattern upon a graph. Different types of residues generate different types of patterns. The interpretation of these patterns requires a certain amount of scientific expertise, since different residues within the same family of chemicals may have similar patterns. A copy of the machine's July 27 printout regarding sample #213833 is attached (Attachment #5).

Since his experience in analyzing patterns describing PCB violations was limited, and since the patterns are similar to those described by other chemicals, Mr. Wong could not be immediately certain that this printout indicated a PCB violation. However, he was aware that the finding was potentially violative, and concluded that there should be further, confirmatory testing. He discussed the problem on July 27 with his supervisors, Ronald Eichner, Supervisory Chemist, and Mitsuo Okamoto, Chemist in Charge, who agreed that further testing was

necessary. The following Monday, July 30, the sample was subjected to confirmatory analysis for PCB residues by the officially approved procedure, known as the Mills Method. A copy of the approved procedure is attached (Attachment #6). According to Mr. Wong, this test indicated that unknown interferences and many chlorinated hydrocarbon pesticides were believed to be present in this sample which might conceivably have led to an inaccurate confirmation. (A copy of this second printout is attached as Attachment #7.)

On August 2, he reviewed the matter further with Dr. Eichner, his immediate supervisor. They subjected the sample to a perchlorination process, which, on August 3, yielded conclusive evidence of PCB contamination in sample #213833 at levels of 15.65 parts per million (ppm). On that same day Dr. Eichner called Dr. Norman Pang of the western regional office for Meat and Poultry Inspection in Alameda, California and reported the information regarding this violation.

The Alameda office is responsible for meat and poultry inspection in the 14-State western region. The office is directed by L. J. Rafoth, and his assistant, M. C. McNay. They supervise a staff of six professionals, including two veterinarians who specialize in slaughtering. Norman Pang specializes in the meat area, Michael Nusias in poultry. Most of Dr. Pang's working responsibilities are devoted to residue problems, since that office has found that the predominance of residue violations have occurred in the red meat area. Dr. Nusias, however, spends approximately one half of his time on residues, and one half of his time on other matters, primarily involving poultry.

Ordinarily the call received by Dr. Pang on August 3, would have been received by Dr. Nusias, since it involved a poultry sample. However, the two veterinarians assist and supplement each others' work. They both have stated that they do not remember specifically, but believe that the call was received after Dr. Nusias, whose assigned work hours begin before those of Dr. Pang, had left for the day. Since the call was received relatively late in the day, Dr. Pang did not attempt to contact any FSQS employees in the field, which are in the Rocky Mountain, as opposed to the Pacific time zone, and are therefore 1 hour ahead in time. Instead, he left a note for Dr. Nusias regarding the matter expecting him to followup on the violation on the following Monday, August 6.

During this same July 16-August 3 period, the following events took place in the FSQS Egg Products Inspection Program. On July 17, pursuant to the random quarterly egg products inspection program described above, an egg product sample of whole egg was taken from Frazier Poultry Farms, Pocatello, Idaho for chlorinated hydrocarbons residue testing at the PDQ Laboratory in Gastonia, North Carolina, directed by Dr. David Frahm. This sample was subsequently tested by procedures similar to those described above. Testing was completed on August 1, 1979. Due to laboratory error this sample was incorrectly interpreted as indicating no violation. A copy of the laboratory certification is attached (Attachment #8).

August 6-10.

Dr. Nusias read the note from Dr. Pang regarding the Jolly sample on Monday, August 6. On the same day he contacted Dr. Boyer at Jolly to inform him of the violation. Since the completed form MP 23-1 for sample #213833 did not include a listing of the name and address of the owner of the chickens, Dr. Nusias requested that Dr. Boyer identify this owner as quickly as possible, so that the regional office could take further steps to deal with the residue problem.

Dr. Nusias initiated a followup call to the Boulder area office on this violation on August 9. (The office's form recording this message is attached (Attachment #9).) This was the first time that Dr. Huber was aware that the sample he had first discussed with Dr. Boyer on July 16 was violative. Dr. Huber then contacted Dr. Boyer about the matter on the same day.

Before speaking to Dr. Huber on August 9, Dr. Boyer was apparently not certain that he was dealing with a PCB residue problem. He indicated that Dr. Nusias, who speaks with something of an accent, was difficult to understand. While he knew from the August 6 telephone call that sample #213833 was violative, he at first felt that he might be tracing a DES residue problem rather than one involving PCBs. Dr. Boyer has stated that he was more familiar with problems associated with DES and had had little experience with PCB problems prior to this incident.

Dr. Boyer indicated that he encountered some difficulty between August 6 and August 9 getting Andrew Jolly, proprietor of Jolly, to tell him the original owner of the chicken from which sample #213833 was taken. As Dr. Boyer stated, "everyday he (Jolly) had a different excuse." He said he was told that a particular secretary would have the information, but she was not in the office on Thursday, August 9. After a few phone calls between the two veterinarians and conversations with Andrew Jolly, the source of the contaminated birds was identified as the Ritewood Egg Company, Franklin, Idaho, on August 10. This information was immediately relayed to Dr. Nusias in Alameda. Dr. Nusias then began to draft the routine letter that is sent to the owner of the product containing a violative residue. He completed his initial draft of this letter on the same day, and gave it to a clerical assistant for typing.

August 13-17.

Dr. Nusias spent the following week, August 13-17 in Denton, Texas, attending meetings involving the review of techniques for modified traditional poultry inspection. After Dr. Nusias' initial draft of the letter to Ritewood Farms was typed, Dr. Pang, who remained in the Alameda office, reviewed the letter. Dr. Nusias and Dr. Pang currently share the use of one full-time clerical assistant. They are responsible for the initial drafting and processing of all residue violation letters within the region; their office processes approximately 500 such letters per year. Procedures in the regional office require

that either Dr. Pang or Dr. Nusias initial such a letter prior to its submission to the director or assistant director for signature. In reviewing the draft, Dr. Pang decided to make a few revisions, including a specification of the term "Polychlorinated Biphenyls" and a few other editorial changes. The letter was retyped with these revisions and resubmitted to Dr. Pang on August 16.

In addition to Dr. Nusias' absence, Dr. Rafoth was on annual leave during the week of August 13-17. Since Dr. McNay was involved in other business and not immediately available, Dr. Pang himself signed the letter for Dr. Rafoth when it was resubmitted to him on August 16. A copy of this letter is attached (Attachment #10).

In addition to the addressee, copies of this letter were sent to a number of other State and Federal officials listed as recipients on Attachment #10 including area MPI officials, residue evaluation personnel in Washington, representatives of the EPA and FDA, and Idaho State officials.

Prior to his signature of the August 16 letter, Dr. Pang made a number of telephone calls regarding the violation. On August 14 or 15, he contacted Dr. Joseph A. Jones, the Assistant Area Supervisor in Boulder, who was acting for Dr. Huber. During the week of August 13-17, Dr. Huber was in the Alameda office for general supervisory meetings. Dr. Pang also called Dr. William Leese, National Residue Coordinator in Washington, D.C., to alert him of their problem.

These individuals immediately took steps to coordinate an effort to trace product shipped out of Jolly to its customers at the time the violative residues were detected. Product shipped to Swift and Company, Clinton, Iowa (Federal Establishment P-76) (Swift) in late July was identified and detained for testing. This involved communication with compliance and meat inspection personnel in the North Central Region, where Swift is located.

On August 17, information on Swift product derived from chickens purchased from Jolly was transmitted from the North Central Region to Dr. Leese (Attachment #11). As this memorandum indicates, 30 bird samples were collected and submitted for laboratory analysis on August 20.

On August 15, Dr. Pang had also contacted a representative of the FDA regarding the violation. Normally, FDA is notified by a copy of the violation letter. However, Dr. Pang decided to accelerate this process since the violator (Ritewood) also produced eggs and any contaminated shelled eggs would lie within FDA's area of jurisdiction. He contacted James Davis, the Chief Investigator in FDA's Seattle office by phone on August 15 to advise him of the problem. Mr. Davis did not specify to Dr. Pang exactly what action his agency might take based upon this information.

Dr. Pang also telephoned Sam Traylor, Assistant Regional Director of the Stockton, California area office (currently located in Modesto,

California) of PDQ and discussed the violation on August 15. Again, Dr. Pang felt that a violation involving an egg company might come within the regulatory responsibilities of this other office. Mr. Traylor informed Dr. Pang that this would become a matter of PDQ responsibility only if it involved egg products processing, since the Egg Products Inspection Act is specific regarding the responsibility and authority of the USDA concerning egg products.

August 20-24.

Copies of the August 16 letter were received by Ritewood Farms on August 19; FDA and the Boulder area office received their copy early in the week of August 20. FDA's investigation at Ritewood began on August 20. Dr. Huber returned to the Boulder office on this same date and followed up on Dr. Jones' work in tracing of product shipped out of the Jolly facility to Swift. This involved followup calls, and the matching of records obtained from Swift and from Jolly. Testing on the Swift samples submitted for laboratory analysis on August 20 were completed on August 24. They revealed consistently violative levels of PCB in the poultry which had been shipped from Ritewood, slaughtered by Jolly, and processed by Swift.

FDA started its investigation at Ritewood Farms, Franklin, Idaho on August 20. Dr. Huber was in frequent contact during the entire week with Mr. Marlow Woodward, who is the Ritewood owner, and with representatives of the Alameda office. His primary function was to coordinate the followup testing of additional birds from Ritewood.

On August 21, in Provo, Dr. Boyer took 30 samples of 59 birds shipped by Ritewood to Jolly on August 20 for pretesting (forms are Attachments #12-14). These were packed in three separate boxes and shipped, on the same day, to the San Francisco laboratory. They were received in the laboratory on August 23 and testing was begun on the 24th.

During this week, Mr. Woodward expressed a number of concerns to Dr. Huber by telephone. He particularly emphasized that he could not understand why he was not advised, through the Department's August 16 letter or through any other source, of the possible problem of egg contamination.

August 27-31.

The pretesting of the samples of Ritewood chickens was completed in the San Francisco laboratory on August 27. Dr. Eichner telephoned Dr. Boyer directly on August 27 informing him of the high levels of PCB found on the pretest (36 to 67 ppm). Another letter confirmed these results and was prepared in the Alameda office and signed by Dr. Rafoth on August 31 (Attachment #15).

During this week V. L. Hutchings, Compliance Officer-In-Charge for the Western Region, became aware of the problem for the first time through Dr. Pang. While no specific requests for action on his part were made, he did assign a Compliance officer, Charles Anderson, to

attend meetings with State officials on the topic and to keep him advised of any developments. He also relayed the information to John Gould, Deputy Director of Compliance's Evaluation and Enforcement Staff in Washington, D.C. Mr. Gould told Mr. Hutchings to continue to keep him informed if problems arose.

On August 29, Sam Traylor of the PDQ office in Stockton was contacted by a representative of the Idaho State Department of Agriculture informing him that egg products might be involved in the PCB contamination incident. In addition, he informed Mr. Traylor that ungraded eggs had been shipped from Ritewood Farms to an egg product breaking plant in Salt Lake City, Utah (Salt Lake Egg Farm), and Pocatello, Idaho (Frazier Poultry Farms). These plants are within the jurisdiction of USDA (PDQ). This information was relayed to Howard Magwire, National Supervisor, Egg Products, in Washington, on August 30.

After discussions concerning this report with Idaho officials, it was determined that John Osborn, a supervisor in the Stockton office, would go into the field in order to investigate this problem the next day (August 31). Mr. Osborn took about fourteen (14) "library" samples at Frazier going back 60 days and forwarded them on August 31 to the PDQ Laboratory in Gastonia, North Carolina for analysis.

He also found during his investigation that Frazier had 67 customers who could have received potentially contaminated egg products.

Additionally, he found that eggs were also being broken at Spokane, (Commercial Creamery) and Marysville, Washington (Pacific Egg Products Northwest); and pullets were going from Ritewood Farms to Oakdell Farms, Riverton, Utah. Mr. Osborn coordinated his followup efforts with the FDA and representatives from affected States.

On August 31 extensive efforts were being made at Ritewood to attempt to identify the source of contamination. Eggs were systematically being resampled along with replacement and laying birds not sampled by USDA. Feed, water, and even air were considered possible sources of contamination.

September 3-7.

On September 3 Mr. Woodward (Ritewood) advised Dr. Huber that he had obtained permission from EPA for deep burial of the contaminated flock. On September 4 Ritewood voluntarily discontinued marketing its eggs as of the September 3 production. On the same day Ritewood also received the certified letter dated August 31 from MPI-Alameda, which gave notice of the results of the August 21 pretesting of Ritewood's birds indicating PCB levels of from 36 to 67 ppm.

On September 6 FDA collected samples at Ritewood of meat and bone meal delivered from various suppliers between May 16 and August 14. They also sampled other feed ingredients and products not previously sampled including dust and feed residue. Air sampling was continued.

Between September 3 and 7, PDQ's Laboratory in Gastonia began to receive the results of testing of the Frazier "library" samples. In addition a re-evaluation of the Frazier egg product sample taken on July 17 and previously reported as negative for PCB was found to be positive. Upon conclusion of the testing it was shown that PCB contamination had been present in the Frazier samples since about July 17.

September 10-16.

Howard Magwire was sent a memorandum dated September 10 by the State of Idaho, Department of Agriculture, Bureau of Inspection and Compliance, regarding the details of an egg product recall. It was noted in the memorandum that the cooperation by Frazier and his distributors regarding this matter had been very good and that final laboratory results were obtained of all samples that morning. The USDA and the State of Idaho cooperated in monitoring this recall.

During this period FDA continued its investigation to determine the source of the problem, and representatives of all interested agencies continued their own efforts to find and recover contaminated products. On September 12, the North Central Region notified Dr. Harold Trabosh, Senior Staff Officer, Epidemiology, Science, FSQS, that Campbell Soup Company (Federal Establishment #26) had received chicken meat contaminated with PCB residues from Cherry Lane Farms, Three Forks, Montana; and Montana Farms, Townsend, Montana.

Dr. Trabosh relayed this information to FDA representatives in Rockville, Maryland, pointing out that the investigation should focus upon a common source of feed between these two suppliers and Ritewood.

On September 12 Marlow Woodward (Ritewood) received a notice from FDA that a sample of meat meal delivered on June 26, 1979, from Pierce was highly contaminated with PCBs. On September 13 Dr. Huber was advised of the possible involvement of Pierce Packing and was also informed that feed from Pierce was also being fed to turkeys in Utah. On the next day, September 14, Dr. Huber spoke to a representative of the Utah Department of Agriculture who expressed disappointment in not being notified of the initial PCB violation in Franklin, Idaho (just over the Utah State Line). The State of Idaho Department of Agriculture was also in contact with Dr. Huber on this date in their efforts to assist Mr. Woodward.

On September 13, Dr. Michael J. Conley, relief veterinarian who had responsibility at that time for operations at Pierce, and Dr. Carl Nash, circuit supervisor in the area, were contacted by Charles Breen, a field investigator for FDA. This was the first time either had been told that Pierce was the possible source of the PCB residue problem. Dr. Nash contacted his immediate supervisor, Dr. Vernon Spears, the acting area supervisor, about this matter on the same day.

Dr. Spears in turn called Dr. Nusias and suggested that he be allowed to institute an immediate emergency sampling plan in the area. Dr. Nusias advised him to await further instruction.

On Saturday, September 15, a representative of Pierce told Dr. Nash that a meeting was to be conducted the following morning at the Pierce establishment at the request of FDA. Dr. Nash attended. Those present were advised that FDA had concluded that a transformer accident back in June was the source of the PCB contamination. A Pierce engineer had alerted FDA to the transformer as a potential source of the problem. Cleanup measures were instituted by Pierce on the same day.

Analysis: June to September 16.

The chronology of events between June and September 16 reveals a number of problems in the FSQS response to the PCB contamination. The following paragraphs further explore the questions of what worked well, what did not, and why. In some instances, the analysis points towards possible solutions. Many of the solutions suggested here are later treated more systematically in the final section of the report. The issues are discussed below under four separate headings. Meat and Poultry Inspection, Science, Commodity Services, and overall policy and administration.

1. Meat and Poultry Inspection. Meat and Poultry Inspection (MPI) personnel in FSQS are responsible (1) for general control, including sanitation responsibilities, in federally inspected establishments; (2) for physically taking and preparing samples and for submitting them to the appropriate laboratory for testing; (3) determining the source of the violative tissue (if this is not already known) upon notification of a violation; (4) for formally notifying the suspect grower and other interested parties of the violation; and (5) for instituting followup measures, through the appropriate field offices, to coordinate and effectively deal with a problem which has been identified.

General responsibilities within MPI for sanitation and overall plant maintenance are relevant to the PCB incident because the accident which lead to the contamination occurred within a federally inspected facility, Pierce Packing Company. The question should be raised as to whether the Agency could have acted to preclude the occurrence of the accident in the first place. There does not appear to be any failure on the part of in-plant personnel in this area. There has been no suggestion that Pierce's storage of the transformer was in violation of any Agency guidelines or directives, either formal or informal. Moreover, there is nothing on record to indicate that Pierce has or is generating special problems in the area of sanitation or overall compliance with inspection requirements. In hindsight, Pierce should not have stored its transformer so close to its drainage system for diversion into animal feed processing. This decision reflects the general lack of knowledge admitted by both Pierce representatives and

Agency personnel within FSQS, of the presence of PCBs in such equipment, and also, ignorance of the highly toxic nature of such substances. Until a ban of PCBs from federally inspected plants can be carried out, storage of transformers and other equipment containing PCB's can and should be more tightly controlled. Whenever possible, such equipment should be segregated within the establishment, and should not be contiguous with any type of processing operation.

More generally, there is a need to expand the sensitivity of both plant and industry personnel to such questions. The inspector realizes that he is generally responsible for the sanitation of the facility. It is obviously much easier for this responsibility to be understood and executed by the inspector if he is dealing with something concrete like a dirty floor rather than with an invisible toxic substance. The inspector and the plant operator must therefore be educated in the direction of equating the former with the latter.

The need for prompt handling of samples must also be stressed. In this specific incident, the Agency has acknowledged unjustified delays in the submission of the original samples, based upon simple human error. Obviously such errors can and should be kept to an absolute minimum. One suggestion in this area worth implementing is some type of tighter control through the regional or area offices to check to see that samples have been processed in a timely manner.

It must also be recognized, however, that the sampling program, under its present design, is not equipped to identify the problems of contamination as soon as they occur within the food chain. There was a 1-week delay in the submission of the sample for testing. This led to a 1-week delay in the overall process. However, even if the sample in question had been mailed on the appropriate day, the period of several weeks would still have elapsed between the time the original accident occurred and the time that the source of the contamination was identified. This problem is a logical extension of the Agency's existing authority and present allocation of resources.

There still is room for other improvement in the area of sampling. In this instance, if the source of the poultry had been identified on the original Form MP-23-1, the regional office would have been in a position to prepare the appropriate notification letter as soon as it knew of the violation. Since this information was not specified, it had to wait until this information was obtained from the field. Inspection personnel must be advised that this information should be placed on any sample form except under the most exceptional circumstances. This aspect of the incident again reflects the general lack of sensitivity to problems in this area and the need for more education.

With regard to the next area of responsibility, notification, it appears that MPI personnel in the Alameda regional office considered the original notification of a PCB violation as a routine matter of business and proceeded accordingly. Within 2 weeks, they had ascertained the

source of the violative tissue, prepared and transmitted the appropriate letter of notification, and contacted representatives of the Food and Drug Administration and of Poultry and Dairy Quality Division, Commodity Services, regarding the violation. The question raised is whether this violation should in fact have been treated as routine. In proceeding in this fashion, MPI personnel acted in accordance with Agency procedures as they existed at that time. FSQS has already taken steps through the development of its Contamination Response System (CRS), discussed in detail in Part IV of the report, to guarantee that such incidents are given higher priority in the future.

The question of whether MPI fulfilled its overall coordination responsibilities once the incident became widespread is difficult because the question is general, and yet calls for an evaluation of a number of specific actions taken by a number of specific individuals. It is clear, however, that efforts were not effectively coordinated at the regional level. There was also confusion over the extent to which MPI personnel were subject to the direction of representatives the Science staff in Washington as opposed to the regular MPI chain of command.

2. Science. Science responsibilities in the residue area include (1) development of the yearly and monthly residue sampling plans; (2) testing, in field laboratories, of meat and poultry tissues for possible residue violations; and (3) overall coordination responsibilities once a problem has been identified.

In developing yearly and monthly sampling plans the goal of the Science staff appears relatively simple and straightforward: utilize existing resources in the most effective possible manner in order to maximize the agency's ability to detect problems of residue contamination. To suggest that there simply be more testing for PCBs would appear to be too narrow a perspective; if available resources are taken as a constant, such an increase must result in a decrease of sampling in an area which might be just as significant from a public health point of view. It is clear that the PCB incident raises basic questions about the adequacy of resources devoted to the residue program, and about the design and purpose of the present program. These questions are discussed at some length in Part IV of the report.

The PCB incident raises further questions concerning the agency's present laboratory capacity. There is no basis to criticize the Science laboratory's performance on the testing of the original sample. Proper procedures were employed and the turn-around target times were met. Obviously it takes longer to complete two tests than it does one; but since the vast majority of non-violative samples can be determined by relatively quick and inexpensive screening tests, the two-step process appears to be an appropriate utilization of resources.

The San Francisco laboratory was worked very heavily once the crisis developed. As the emphasis in the laboratory shifted to surveillance testing of product suspected of being contaminated with the PCBs, there was a complementary decrease in the laboratory's responsibilities

in the random testing area. In the future, the agency must be prepared to activate more laboratory resources when a crisis of this nature develops so that it can deal with the crisis while continuing to meet ongoing responsibilities. The answer appears to be a streamlining of procedures to facilitate use of State-operated and privately-owned laboratories. Private capabilities at large federally-inspected plants should also be more fully explored. Such a system at the Campbell's plant in Iowa was the source of valuable information during the recent incident.

Science's ability to coordinate in the detection area is very much limited by the existing division of responsibilities within the Federal Government. FDA is primarily responsible for the conduct of an investigation once a problem has been identified. USDA's role is, therefore, secondary, supportive, and unstructured. In addition, questions of confusion in the division of authority between Science and MPI personnel has already been noted above.

3. Commodity Services. The Poultry and Quality Division (PDQ) of Commodity Services retains comprehensive responsibilities for all aspects of egg products inspection, including development of a sampling system, actual sampling, inspection, laboratory analysis, and overall coordination in the field.

It is therefore possible to evaluate PDQ performance in this incident almost as a separate entity. They took their own sample and submitted

it to their own laboratory. A testing error was made. They became actively involved in the area only upon notification from the State of Idaho on August 29 that egg products were likely involved. They then proceeded to conduct their own field research. It would be unfair to infer from the one human error that the laboratory is not capable of executing its technical testing responsibilities. In fact, a review of the procedures used by the laboratory have since shown that the problem was not procedural. Efforts have been made, however, to prevent recurrence of the error, and additionally, to increase communication with the Science Staff.

The separate status of the PDQ laboratory may seem unusual from the standpoint of the organizational structure of FSQS. The laboratory also serves the poultry and egg grading program (a fee supported program), and since procedures for the testing of egg samples are somewhat different from those of meat and poultry, there is basis for a separate laboratory. It appears that incident itself has led to improved communication between the laboratory personnel and Science personnel and a general improvement in communication between PDQ personnel and other members of the agency.

4. General: Policy and Administration. There is a need for substantial improvement in clarifying and coordinating the division of responsibility between FSQS and other Federal agencies, particularly

the Food and Drug Administration (FDA). FSQS communication with FDA surely could have been better, but it is worth noting that FDA's communication back to FSQS was no better. It appears, at least in the field, that almost all contact with FDA was initiated by USDA personnel, as opposed to vice versa. A strengthening of existing memorandum of understanding to provide for clear procedural responsibilities by both agencies is a logical starting point. More generally, there must be a strengthening of contacts and communication at all levels of various agencies.

There is wide consensus within FSQS that there is a need for expansion in the feed testing area. The contaminated Pierce feed was the first step in the food chain which led to the widespread contamination. Hence, it was the first place where the problem could conceivably have been detected. Contaminated animal feed has repeatedly been traced as the source of a wide number of residue contamination problems in the recent years. This is currently an area of exclusive FDA jurisdiction. The Agency should insist that FDA efforts in this area be expanded with whatever assistance FSQS is able to provide.

There is also a need for a more structured use of FSQS Compliance personnel, who are responsible for meat and poultry products in commerce once they leave the Federal inspected establishment. Compliance personnel in the field seem to have been notified of the problem by MPI personnel almost as an afterthought, and they often had to take action strictly on their own initiative. The result was a lack of coordinated activity by the Agency in the field. Compliance officials should be

notified early because contamination incidents of this type almost always involve the existence of adulterated product in commerce. A number of these problems that became evident during the discovery phase (July to September 16), appeared in even greater relief as the Agency attempted to mobilize its resources to contain and clean up the contamination. In addition, a number of new problems emerged.

B. The Struggle to Clean Up: September 16 to the Present

With the discovery on September 16 of the source of the contamination at Pierce Packing Company in Billings, Montana, the government knew it had a serious problem. Pierce supplied feed to over 1,400 companies in the United States, all or part of which was contaminated with over 200 gallons of a toxic chemical. Scores of agents from the Food and Drug Administration, and the Food Safety and Quality Service of USDA scoured the region, looking at farms, slaughter and processing facilities, and records. In many parts of the country, buyers began to draw back from their usual suppliers, as word of the contamination spread. Product piled up in slaughterhouses, or was held voluntarily at various points in the food production chain. Over 2,500 samples were taken and analyzed in USDA labs around the country. As possible contamination reached into 20 states and 2 foreign countries, the resources of USDA were taxed to their limit. Private firms were enlisted to analyze samples, and gerryrigged certification programs were started to get product rolling to the marketplace again. On at least two occasions, USDA officials were worried that massive recalls of

turkeys would have to be instituted during the weeks preceding Thanksgiving. On both occasions, that grim eventuality was averted.

To reconstruct all of this, and more, in a strict chronology would be extremely difficult because of the fast paced nature of events and the number of actors involved. In this section, therefore, we have chosen to present the material as a catalogue of the problems that became apparent during the struggle to clean up. Most of the problems identified during this phase of the operation, which still continues, are procedural or management in nature, although some highlight the poorly understood nature of the current residue program and the lack of specific authority by the Federal government. The problems are grouped under seven topics:

1. Level of Awareness
2. Authority to Detain, Quarantine and Destroy
3. Sample Collection and Analysis
4. The Availability and Use of Distribution Data
5. Certification Programs
6. Federal-State Relations
7. Management of the Problem.

1. Level of Awareness

Two problems emerge regarding the "level of awareness" associated with PCB contamination. The first is specific to FSQS. The Agency was

not adequately aware of how widespread PCB contamination can become in a short period of time. The Agency tended to treat a PCB violation as an isolated incident rather than an indication of a potentially far-reaching problem. The second problem is more general and relates to the public's skepticism and confusion about the seriousness of PCB contamination. The actions and public statements of FSQS frequently contributed to this misunderstanding among the public.

Agency Awareness: The previous section noted that the routine handling of the first violative sample led to several delays in July and August. This lack of awareness during the initial stages also greatly hampered the clean-up effort that began on September 16 after the source of contamination had been traced to Pierce Packing Company. For the most part, the clean-up effort began without the benefit of advance planning. The Agency's regulatory machinery jerked into motion in the absence of the prior contingency planning that is essential if large organizations are to move with efficiency and dispatch. Sampling plans were devised on the spot, samples began to pile up in labs, and the paths of compliance officers criss-crossed over several western States. It often seemed as though the Agency had headed off in all directions at once. A great many people worked very hard, but their jobs would have been easier if greater initial awareness on the part of FSQS had led to more contingency planning.

Up until now, FSQS has tended to underestimate the likelihood of extensive PCB contamination. A recent Office of Technology

Assessment Working Paper,[1/] for example, ranked PCB as the environmental contaminant most likely to enter the food supply and present a hazard to human health. Clearly, the Agency's basic instructions and response procedures should reflect the potential dangers of this type of contamination.

Public Awareness: During the clean-up phase of the recent PCB incident, various officials expressed their views as to the overall seriousness of the incident and the potential for adverse human health effects. There was a diversity--even a confusion--of personal and "expert" opinion that contributed to the skepticism and confusion on the part of producers and consumers. The following statements appeared in news accounts:

--". . .no one would be harmed who ate one of the turkeys that had about 3 ppm of PCBs. . .a person who ate the entire flock of 28,000 birds on successive days might be exposed to a minimum risk. PCBs have been linked to cancer only in animals. . ."

--". . .it is our best judgment that the short-term nature of this incident and the levels of contamination found so far pose no immediate threat to the health of consumers in the affected states. . ."

--". . .The PCB quantities in these birds are so slight that any of them--any of them--could safely be eaten. . ."

--". . .I ate a turkey sandwich today, I'll eat one tomorrow, and I'll eat one again for Thanksgiving. . ."

--". . .The only level of PCB I would be willing to eat if I had a choice is zero. But if I had a turkey in my freezer at three parts per million of PCB, I don't think I would want to throw it out, but I don't really know. . ."

--". . .My feeling is that consumption of a few items at or near tolerance levels probably will not be harmful. It's strictly a personal opinion."

During this incident all statements by Federal officials should have been consistent with government-wide regulatory policy addressing environmental contaminants, such as PCBs.

The Regulatory Council's[2/] cancer policy is an excellent model for the type of guidelines that might be adopted for official statements on the human risks associated with food contamination. On October 17, 1979, the Regulatory Council published in the Federal Register, "Statement of Regulation of Chemical Carcinogens: Policy and Request for Public Comments (FR 60038)." Its states:

--A substance that causes cancer in animals, when tested under appropriate conditions, will be considered a potential human carcinogen.

--Animal tests provide valid information even though the dosage administered to the animals may be higher than humans are likely to experience.

--Because there is no currently recognized method for determining a no-effect level for a carcinogen in an exposed population, substances identified as carcinogens will be considered capable of causing or contributing to the development of cancer even at the lowest doses of exposure.

In August 1979, the Toxic Substances Strategy Committee[3/] completed a 2-year study on the regulation of toxic chemicals. Their report[4/] suggested that Federal agencies "should seek to educate the public about policies and procedures that are currently widely misunderstood. . .(including the) use of laboratory animal tests to determine potential human carcinogenicity, and the fact that there is no current method for determining a 'safe' level for human exposure to a carcinogen. Wide public understanding is the joint responsibility of all Federal agencies involved."

FSQS is an active participant in the Interagency Regulatory Liaison Group (IRLG),[5/] one of whose goals is to promote the consistent dissemination of information to the public. It should be possible for FSQS to work through the IRLG to ensure that the appropriate information and education materials are generally available to distribute to consumers (including agency employees) and producers, especially during an incident involving environmental contamination. These materials should be written in "plain English" and should be candid about what is and what is not known.

2. Authority to Detain, Quarantine and Destroy.

The recent PCB incident demonstrates that the Agency does not have adequate legal authority to conduct an orderly and efficient cleanup following the identification of wide-spread environmental contamination. There are at least three possible types of legal authority to prevent the movement of potentially contaminated meat, poultry, and egg products: (1) the authority to hold for testing and destroy, if necessary, shipments that may be contaminated; (2) quarantine authority, and (3) authority to destroy contaminated livestock at locations other than federally inspected plants.

The Agency has only the first type of authority. After September 16, 1979, the Agency began placing hold and test restrictions at Federal plants on all meat and poultry products that had originated from producers or areas known to have received contaminated feed products.

The Agency does not have quarantine authority to restrict the movement of livestock from the farm or other intermediate points in the production chain. However, quarantines have been imposed by States in past contamination incidents. In 1974 and 1975, 500 farms were quarantined in Michigan following the PBB contamination. In 1975, New York State authority was used to impose a quarantine on farms following violative endrin residues.

In the recent incident, the Agency asked the States involved to impose a quarantine. The State of Idaho used selective "retaining orders" to direct farms to stop sales and to stop using potentially contaminated feed. However, the State of Montana, the primary affected State, did not impose a quarantine because Montana law would then require indemnification for losses.

A quarantine could have allowed for a more orderly cleanup process in the State of Montana. State authorities estimated that 300 to 400 Montana hog producers may have used contaminated feed. Because of this widespread contamination, the Agency placed hold and test restrictions on all potentially contaminated meat and poultry when it reached Federal plants. The Agency had no control, however, over contaminated livestock remaining on the producer's premises, which could be sold out of State at distant markets, could be transferred to another producer's location, or could be sold locally for private consumption. Because the State of Montana refused to impose a quarantine, the Agency is now faced with the long-term problem of having to monitor the location and status of all contaminated herds and flocks that have not been destroyed.

What would have been the effect of a quarantine in Montana? The market would probably have shut down temporarily, but that happened very quickly anyway without a quarantine. The following advantages can be identified:

--The slaughterhouses would not incur the costs of holding a large volume of suspect products. In the recent incident, the holding capacity of Montana slaughterhouses was quickly exceeded.

--Fewer surveillance samples would need to be taken, thereby freeing laboratory capacity for monitoring samples, compliance samples, or certification samples. The great number of surveillance samples from Montana in early October contributed to a laboratory backlog that soon grew to 2 or 3 weeks.

--The Agency would know the location of suspect animals and know that they could not be legally moved.

--The Agency would be more confident that all violative products were detected because all producers identified as receiving contaminated feed would be thoroughly tested before the quarantine on them would be lifted.

--For producers not on distribution lists, the market could be reopened in a more orderly fashion and with more confidence that only "clean" products were being received.

The above advantages assume that comprehensive distribution lists can be made available in a timely fashion. (See pp. 63-66 on distribution data). They also assume that a quarantine can be imposed when contamination is suspected, rather than confirmed. If a quarantine can

be imposed only at locations known to have contaminated animals, then its value is limited, because many animals could be moved before the necessary confirmatory tests were complete. As part of the legislative proposal (See Part IV), the Agency is requesting the authority to quarantine livestock and poultry when the Secretary has the reason to believe they may contain unlawful residues of pesticides, drugs, and other chemical substances. The need for quarantine authority at the Federal level to control residue-contaminated livestock is not a new issue. The USDA reported to GAO that it would seek enhanced authority in the 95th Congress (The Comptroller General of the U.S., Report to the Congress, No. HRD-77-96, June 8, 1977), and Assistant Secretary Foreman has testified twice before Congress on the need for such authority.

Even without quarantine authority, the Agency can take several steps in this area to prepare for any future incidences. The Agency should know in advance the precise authority that exists in every State. The Agency can also promote cooperative agreements with States. FSQS now has such an agreement with Virginia that provides for a State quarantine in cases involving environmental contaminants.

There is probably no need for the Department to seek the third type of authority, the authority to destroy contaminated animals. The States now have such authority. EPA also has authority concerning the methods and location of disposal. As long as USDA works closely with the States in cleaning up incidents of environmental contamination, the

authority to keep contaminated animals out of the food chain, along with new quarantine authority, would appear to be sufficient.

3. Sample Collection and Analysis.

Several problems associated with the Agency's efforts to collect and analyze samples for PCB violations have been identified.

--The Agency collected more samples than it could analyze, thereby creating a considerable backlog in the laboratories.

--Lack of coordination caused some duplication of effort in sampling.

--There was no system for assigning priorities to surveillance samples awaiting analysis in laboratories.

The Backlog. Three types of meat and poultry samples were collected by the Agency during the cleanup phase: Special monitoring samples, direct surveillance samples, and certification samples. In one sense, all of these samples were surveillance samples because they were collected in addition to the regular monitoring phase of the National Residue Program.

Shortly after September 15, the Agency implemented a "special" monitoring program in an effort to discover the geographic scope of the PCB contamination. This effort was a response to broad guidance from

the Administrator's Office to increase existing monitoring efforts and to expand coverage to include swine (prior to September 16 the incident focused entirely on poultry and eggs). The "special" monitoring program covered the entire Northwest. Establishments, species, sample collection dates, and receiving laboratories were specified by the Headquarters Residue Evaluation Staff. Collection of special monitoring samples began on September 24, 1979. As of November 15, 1,040 monitoring samples had been analyzed for PCB contamination. The breakdown by species is as follows:

Swine	455
Fowl	282
Young Chickens	39
Turkeys	108
Cattle	125
Sheep	13
Duck	3
Geese	14
Goat	1
Total	1,040

During the cleanup phase, the agency also took direct surveillance samples from animals marketed by individual producers known or suspected to have contaminated animals. The Residue Evaluation Staff instructed area offices to sample every lot in areas known to have received contaminated feed products. Records show that sampling from

Montana producers suspected of receiving PCB contaminated feed began on September 20. FDA's identification of more than 20 major brokers and buyers of potentially contaminated meat meal produced by Pierce Packing Company. By September 26, inspectors were taking large numbers of samples in that State. Direct surveillance also included samples taken from products purchased for the school lunch program and products purchased by the military.

Certification samples are similar to direct surveillance samples except that they were initiated by producers who may have used contaminated feed and wanted to market their product. This type of sampling began on October 6. As of November 16, 789 direct surveillance or certification samples had been analyzed for PCB contamination. These samples included the following:

Swine	374
Fowl	142
Young Chickens	72
Turkeys	22
Cattle	14
Ducks	1
School Lunch Program	132
Army	2
Other	30
Total	789

In total, by November 16, the Agency had analyzed over 1,800 samples.

In contrast, the monitoring phase of the National Residue Program analyzed a total of 2,432 samples for all chlorinated hydrocarbons during all of 1978. The rapid increase in sampling caused a backlog in the laboratories that reached 2 to 3 weeks. The resulting confusion was explained in several ways:

--"We overestimated our capabilities."

--"We didn't know our capabilities. We had no contingency plans."

--"The Agency didn't begin using composite sampling and analysis until October 26."

--"Everybody began sampling, not enough time was taken in selecting the most appropriate samples."

The new Contamination Response System (CRS), described in Part IV will provide some of the advance planning necessary to prevent backlogs in the future. Better planning, however, will not completely eliminate the possibility of backlogs in the future. Laboratory capacity will remain finite, and the agency must find ways to reduce the number of samples required. One possibility is better use of information regarding distribution of the contaminated product. The geographic scope of a contamination incident can be determined either through monitoring samples or through distribution data. Readily available, reliable data should reduce the need for extensive monitoring.

Lack of Coordination. While the Residue Evaluation Staff (RES) initiated all special monitoring samples during the recent incident, it did not know which specific surveillance samples were taken until the laboratory analysis forms were forwarded to Headquarters. No one office was responsible for coordinating the sampling effort in order to prevent duplication.

To illustrate, special monitoring samples were taken at the direction of the RES on September 25 and again on September 28 at the Oregon Turkey Growers Association, a large cooperative that slaughters and processes turkeys. The flocks sampled belonged to Charles and Gerald Evers of Dayton, Oregon. On October 1, the agency learned from the Food and Drug Administration that the Evers had purchased a blended tallow for Jacob Stern and Sons, Inc., of Seattle, Washington, who had purchased the tallow from Pierce Packing Company of Billings, Montana. The Agency proceeded to take direct surveillance samples of the Evers flocks on October 2 and October 5 at the Oregon Turkey Growers Association. It does not appear that the collection of monitoring and surveillance samples were coordinated. Directives for monitoring samples originated in Washington, while directives for surveillance samples originated in the area offices.

After the cleanup of the current incident is completed, the Agency should review all samples taken in order to determine what level of monitoring and surveillance would have been most appropriate. It may be possible to generalize and provide guidance as to what level of

monitoring and surveillance is appropriate for different kinds of contamination situations.

Lack of Priorities for Laboratory Analysis. In August 1979, laboratory analysis of a single sample for PCB residues usually took 3 or 4 days.

By the end of September, FSQS laboratories were faced with large backlogs and samples awaiting analysis were delayed for 2 weeks or more.

Because of the large number of samples and limited laboratory capacity, there was an obvious need to decide which samples to process first. Survey samples to determine the extent of the problem were analyzed before samples to determine product compliance and before random monitoring samples. There was no attempt, however, to establish priorities within the large groups of surveillance samples. These samples were handled on a first in, first out basis. Laboratory personnel, upon receiving the large number of surveillance samples generated by the crisis, had no way of knowing which of the various surveillance samples were likely to yield the most useful information and should be analyzed first. In the future, the team coordinating the investigation should establish sample priorities, inform all people responsible for collecting samples of the criteria for determining priorities, and require that each sample form indicate the level of priority for each sample. Such procedures are essential if the Agency's limited laboratory resources are to be utilized efficiently during a contamination crisis.

4. The Availability and Use of Distribution Lists.

The general availability of distribution data is a key element in cleaning up environmental contamination. The availability and timing of distribution data affects the type and number of samples needed to be collected. Other than special monitoring efforts, distribution data provide the only means for determining the geographic scope of a contamination incident. If the agency knows which producers did not receive contaminated product, then it can soon permit the orderly marketing of products without serious concern that contaminated products might reach consumers. In the absence of such information, the Agency must hold product at the plant until it can be tested and cleared.

The Food and Drug Administration has the responsibility and authority to trace the distribution of contaminated feed, such as that which left Pierce Packing Company. FDA has the authority to then go to buyers and brokers to obtain the names and addresses of secondary purchasers, and so on, until they trace the contaminated product down to the level of the user (the producer or farmer). During the PCB incident, FDA chose to trace all shipments of 1,000 lbs or more.

By September 19, FDA had identified more than 20 major brokers and buyers of potentially contaminated meat meal from Pierce Packing Company. An estimated 1.9 million pounds of meat meal were distributed in 6 States--Montana, Idaho, Utah, North Dakota,

Washington and Minnesota, with over 90 percent of the meat meal going to Montana companies.

The collection of distribution data was time-consuming. On September 23, 1979, the Denver Regional Office of FDA estimated it would take another 2 or 3 weeks to complete the tasks. FSQS continued to receive distribution data into December. The Agency has no information for North Dakota--tracing there was handled by the State. As a result, only the early distribution data was very useful to FSQS in cleanup operations.

The early distribution data was useful in identifying large producers who buy bulk meat meal directly for their own mills and in identifying the geographic areas receiving large amounts of contaminated product. In these areas the Agency sampled and detained all market hogs and poultry in federally-inspected plants. Some of the more detailed distribution information is now being used in clearing operations, i.e., identifying recipients of contaminated feed that have already been sampled to determine if those samples are adequate to certify remaining animals as "clean." The most useful information in containing the contamination, however, was the information received in the early stages.

The sampling at the Oregon Turkey Growers Association illustrates the need for prompt transmittal of information. Apparently FDA knew by

September 21 that Jacob and Stern & Son in Seattle, Washington, had purchased tallow from Pierce Packing and was selling blended tallow to two large turkey producers in Oregon. However, FSQS did not receive this information until October 1. In the meantime, FSQS had sampled the Stern flocks under the monitoring phase on September 25 and September 28. Had the Agency received the distribution data earlier, the monitoring samples could have been analyzed on an expedited basis perhaps in time to prevent the shipment of potentially contaminated turkeys to school lunch programs distribution centers in Los Angeles, Salt Lake City, Sioux Falls, Spokane, Seattle and Phoenix. (Fortunately, these turkeys were eventually retained at the distribution centers.)

The lessons from the recent PCB incident are clear: FSQS must work closely with FDA to see that distribution information is transferred more quickly and in a more orderly fashion. FDA has emphasized the need to ensure accuracy before the information is released. There appears to be no reason, however, why FSQS should not have access to preliminary information on the understanding that it is preliminary. In developing sampling plans, even general information, such as estimates of the amount of feed involved, can be useful. In addition, there should be a focal point for sharing information. In the recent clean-up effort, FSQS field personnel frequently received distribution lists without knowing that the people in Wahington devising the sampling plans did not yet have the same lists.

5. Certification Programs.

By the end of September, the poultry and pork markets in Montana had come to a halt. The holding capacity of instate packing plants had been exceeded. All lots were being sampled and held for testing; which was taking 2 or 3 weeks because of the backlogs. Out-of-State plants were boycotting Montana products. Montana officials made an urgent request for help from FSQS in relieving this situation. In response, the Agency sent a task force to Montana to set up certification programs along the lines suggested by Dr. James W. Glosser, Montana State Veterinarian. The purpose was to reestablish the normal flow of marketing and to serve as a model for other States involved.

The certification program was set up in three phases. Phase I began on October 2, 1979. It applied to producers that could provide documentation showing they had never received contaminated feed. To qualify for certification under Phase I of the program, a producer was required to provide the Montana Department of Livestock with:

--Receipts of documents showing the source of all meat meal, protein concentrate and finished feed purchased, delivered, or fed since June 15;

--A statement that no other commercial feed was fed to pigs or chickens;

--A statement of the number of pigs and chickens fed and the amount of feed used;

--A statement of the number of pigs and chickens on inventory to be marketed in the next 6 months; and

--A sworn statement that all information submitted was true, accurate, and complete, and that in the event the submitted inventory was not true, the applicant would assume all liability.

Upon receipt of these materials, the Montana Department of Livestock would then certify that the hogs or poultry were not contaminated with PCB. A certificate stating that the animals were not contaminated would accompany the hogs or fowl from the farm of origin through slaughter and processing.

Phase II was announced on October 9, to assist producers with animals that may have been contaminated by PCB. To qualify for certification under Phase II, Montana pork and poultry producers had to arrange for a representative sample of their current animal inventory to be slaughtered and tested at a federally-inspected plant. Agency personnel worked with large poultry producers to ensure that appropriate samples were taken. The pork producers had to locate a plant that would accept five animals for testing. If the test results were negative, the Montana Department of Livestock would then certify that animals from the herds or flocks sampled were not contaminated

with PCB. After certification, the animals from tested lots could be marketed freely.

Phase III was announced on October 11, to aid the small producers who raise hogs or fowl for home use. To have their animals tested, producers had to contact their local county extension office for sampling instructions. The samples were then sent to USDA-approved laboratories, and USDA paid for the testing. It was later agreed that the USDA would also pay for egg testing and be reimbursed by the FDA.

The gerryrigged certification program appears to have been successful. But before it is used as a model for future contamination incidents, it will be evaluated carefully. The Agency must establish legal authority to assist producers in marketing and also to assist in taking samples on farms. In addition, future certification programs will need to be coordinated carefully with the overall residue sampling program. Finally, certification programs must be designed in a way that does not provide significant loopholes for the marketing of potentially contaminated product.

6. Federal-State Relations.

The recent incident raises the basic question of the proper role of the Federal government vis-a-vis the states. One still widely held view is that environmental contamination is a State problem and the role of the Federal government is to provide technical assistance and advice as

required. The contrasting view, now becoming predominant, is that environmental contamination is a Federal problem. According to this view, FSQS should take the lead whenever meat or poultry products are involved and seek out the assistance of State and local organizations.

The FSQS role in this event was fundamentally different than the past USDA role in such incidents as PBBs in Michigan, and PCBs in the Southeastern States. In those instances, USDA provided assistance, guidance and resources to State and local organizations who were primary actors in containing and cleaning up the contamination. In the recent incident, FSQS, as well as other Federal agencies, played a far more active role. However, FSQS had trouble convincing the affected States, producers, and consumers that the Federal government had the situation well under control. At times, it responded defensively or tentatively, perhaps because it simply had little experience in assuming a strong leadership position.

From the State's viewpoint, the Federal effort in the recent cleanup effort often seemed highly disorganized. The States were confronted with several Federal agencies, each with different authority and different approaches. Because of the States' difficulty in finding a common Federal thread, the National Association of State Departments of Agriculture (NASDA) can be expected to push for a lead Agency concept along with emergency action teams patterned after those in APHIS. Such initiatives are welcome, because they can lead to closer and better-defined Federal-State working relationships.

From the Federal viewpoint, the States, particularly Montana, often appeared uncooperative during the cleanup. One example is Montana's refusal to invoke its quarantine authority. The Montana Department of Livestock maintained a low profile in dealing with producers with contaminated livestock. State officials apparently did not want to be the bearer of bad news to local producers. As a result, the local producers in Montana came to see the Federal government as the cause of destruction of livestock and feed.

The Federal-State cooperation obviously can be improved considerably. The new Contamination Response System should be a step in the right direction. For example, in an "Alert Condition," Field Operations is directed to "maintain contact with the State and prepare for cooperative action." It will be important to know in advance, however, just what type of cooperation can be expected. The Agency now has cooperative agreements with several States and should continue to develop more of the same. These should be reviewed periodically. State and local cooperation is important because success may depend on a strong State organization or trade association that has a close working relationship with producers.

7. Management of the Problem.

The review of the cleanup phase of the recent PCB contamination incident reveals three types of management problems:

--How to maintain control over the ongoing field and headquarters activities;

--How to manage the dissemination of public information, and

--How many Agency resources to commit and when.

Field and Headquarters Coordination. Discussions regarding the management of personnel inevitably focus on the question, "Who is in control?" Control in the recent PCB incident was particularly difficult because the crisis was neither nationwide nor localized. The problem was also complicated by the fact that it occurred far from Headquarters in Washington.

On Monday, September 17, a Headquarters Task Force was formed. This group met daily to address problems and discuss overall direction with the Office of the Administrator. While this provided good communication among top management, it did not establish clear lines of authority over various ongoing operational activities. Different sources within the agency components were releasing information to the public and press, without any overall coordination; the result was inconsistency, and confusion among the public. The Residue Evaluation Staff assumed it had a responsibility for all monitoring and surveillance, and yet samples were apparently initiated by other parts in the Agency. All field activities were supposed to be under the control of the Western Regional Office in Alameda, California. The Regional

Office, however, had direct line authority only over the field personnel in the Meat and Poultry Program, while Field Compliance Officers, Poultry and Dairy Quality personnel, and all laboratory personnel continued to report directly to Washington Headquarters.

By October 1, it became apparent that more direct control was needed over various field activities. A Headquarters task force was sent to Helena, Montana to help State officials and producers coordinate the cleanup activities. This move helped, and probably should have been done earlier, but it was also not a total solution since the problem extended beyond Montana.

Various suggestions have been made to provide for a more coordinated response in the future. One is for the Agency to establish emergency teams similar to those the Animal and Plant Health Inspection Service (APHIS) maintains for outbreaks of foreign animal diseases.

Another suggestion is that modifications be made in the field structure so that Regional and Area Offices have line control over all field operations (MPI, Compliance and PDQ) conducted within the respective regions or areas. The new Contamination Response System (CRS) clarifies responsibilities by placing the Chairman of the CRS in control, and by defining lines of responsibility running to and from the Response Team. The Agency must assess whether the CRS will remove the need to consider emergency action teams or to consider a unified field structure.

Public Information. The Agency was heavily criticized for not speaking candidly at the outset about the extent of the problem and the potential danger to consumers. An article that appeared in the Idaho Statesman on September 19, 1979, illustrates a problem that all agencies face in handling the cleanup phase of an environmental contamination incident. The lead sentence in the article stated, "The U.S. Food and Drug Administration on Tuesday refused to disclose the name of a southern Idaho livestock farm that fed 24,000 pounds of possibly toxic feed to its stock." The article went on to describe the paper's efforts, begun the previous week, to obtain the list of recipients of the contaminated feed.

The problem is what to tell consumers and when. After Ambrose Farms (Wendell, Idaho) was identified as a major recipient of meat meal from Pierce Packing, some Idaho supermarkets took Falls Brand meats off their shelves. (The Independent Meat Company of Twin Falls, Idaho, had purchased hogs from Ambrose Farms and had packaged the meat under the Falls Brand label.) Other food stores continued to sell the product pending test results. What should FSQS have told consumers and retailers in this instance? Formulating a position may not be easy in the absence of conclusive evidence one way or the other, but it is also clear that the Agency must make a statement of some sort. By providing no comment, the Agency appears to be withholding information and creates confusion among the public. It has been suggested that the Agency should have arranged after September 15 for daily press conferences in the area.

One lesson from the recent incident is inescapable: the Agency must attempt to develop an explicit policy on public information. In the absence of an explicit policy, the Agency has tended to release information only sporadically in response to the most pressing inquiries. The underlying assumption of this "implicit policy" was that the Agency did not want to create undue alarm. It is clear, however, that the result was often just the reverse. The public could obviously perceive that there was a possible threat to health, but were left confused about the exact nature of the risk. A more aggressive and open public information policy, rather than creating alarm, actually would have helped to dispel much of the confusion.

The Agency will have to consider a number of difficult questions in devising a public information policy for contamination incidents. Even though the policy should be as open as possible, it obviously is not possible to release every piece of information as soon as it is received. Events can move very quickly, and the Agency itself is often confronted with a welter of tentative and conflicting "facts." It is important to have guidelines on the type of information that should be released, and on the evidence required for release. Since all events will not conform to guidelines constructed in advance, it is also essential that a public information specialist be closely involved with the activities of the response team. As each new development occurs, the following questions should be asked: How soon can we release this information? What confirmatory evidence is required? How can the meaning of this information best be explained to the public?

Finally, the task of informing the public once a contamination incident has occurred will be less difficult if the Agency undertakes a long-range effort to inform the public generally about the risks of chemical contamination of the food supply. This effort will be discussed in some detail in Part IV.

Committment of Resources. On Thursday, September 13, 1979, Dr. Vernon Spears, the Acting Supervisor for the MPI area encompassing Pierce Packing, suggested to the western regional office for MPI in Alameda, California, that he be allowed to institute an immediate emergency sampling plan in his area. Dr. Spear's request raises the policy question of whether increased random sample monitoring for PCBs should have been initiated earlier. Some increased sampling could have followed the August 3 finding of PCB contamination in hens marketed by the Ritewood Egg Company, even though the problem still may have been localized. The FDA sampled meat meal at Ritewood from various suppliers on September 6. On September 13, the Agency learned that meat meal purchased at Pierce Packing was contaminated. At this time, the exact source had not been located, but there was a strong liklihood of widespread feed contamination. Monitoring also could have been increased at that time.

At present, there are no analytical tools for assisting management in making the difficult decision of when to commit additional resources. The Agency should, therefore, consider a study to illustrate how the cost of cleanup increases with time. The recent incident can be used

as a case study to show how each consecutive week increased the total cost in terms of feed, animals and products destroyed, and in terms of Federal, State and local resources required. Such a study would provide guidance in the future for selecting the optimum times and places for committing additional resources. As the recent incident shows, the cleanup effort can be hampered by acting both too early and too late. The study can also be used to evaluate internal Agency procedures and proposed changes to these procedures.

C. Summary of the Problems

The preceding sections have revealed a catalogue of problems. Mere statement of the problems provides no assurance that they will not occur again. In order to construct lasting solutions to these problems, the Agency must find out why they occurred. It must look for common threads and for causes. It must ask: What problems are avoidable? What past assumptions have been brought into question? What problems result from the limitations of technology? What problems might be corrected by a different allocation of resources? What problems require long-term solutions? Does the Agency have sufficient legal authority to deal with incidents of environmental contamination? Is the present design of the residue monitoring program adequate? As the agency asks these questions and as it begins to construct solutions, it is useful to group the problems according to the following categories.

Educational-Awareness Problems: Neither USDA employees nor the general public are sufficiently conscious of the potential health problems that can arise from environmental contaminants like PCBs. This is the only conclusion that can be drawn from the time lag in some USDA offices, and the confusion that often surrounded the recent incident. It may also be true that Washington level program officials are operating under a misconception that environmental contamination problems are usually small and easily containable. This problem is attributable to the emerging nature of the toxic substances revolution in the United States, as well as to the relative newness of the National Residue Program within a very well established inspection program that has historically concentrated on different kinds of human and animal health hazards.

Management-Procedural Problems: It is clear that better emergency response mechanisms are needed once a problem is discovered, as well as stronger emphasis on the efficient handling of monitoring samples at every point in the process. Laboratory capability is probably adequate, but the development of optimal sampling plans under conditions of stress are necessary. The "shotgun sampling" approach initially adopted by the agency was understandable in the absence of a previously agreed upon approach, but was ultimately counterproductive in handling the problem. The focus of responsibility was unclear, both at headquarters and in the field; this led to both operational and information problems with the States, Federal agencies, and the public. Finally, the cleanup problems highlight continuing organizational problems within USDA, as the FSQS, a new agency, attempts to knit related but different programs together.

Regulatory Problems. The unspoken problem of the entire incident is the continuing use of PCBs and other environmental contaminants in the food production system. The current division of responsibility among USDA, FDA and the Environmental Protection Agency practically ensures that uniform and coherent regulatory policy will be difficult to obtain. Besides coordination, difficult regulatory problems hinge on the ability to dispose of the material safely, alternatives that are available for its cooling uses, and available technology to purge PCBs from existing systems.

Legislative Problems: The ability of the government to wrestle effectively with the environmental contamination problem rests in part on its ability to identify and contain problems once they occur. As the previous sections point out, no State was willing to invoke its own quarantine provisions to isolate suspected animals on the farm; in the absence of any identification authority, the time it took to locate the original owner of the contaminated sample was also considerably longer than it might have been.

Budget-Conceptual Problems: Even with no procedural or "awareness" problems, the program still would have taken over a month to detect the contamination. In fact, the ultimate discovery of the PCB contamination could be described as an "accident." The response time problem is directly related to the monitoring rather than regulatory nature of the program. The monitoring program is a concept developed because of a perception of limited resources that can be spent on

residue problems, as well as conceptual limits on the design of an effective regulatory program within reasonable financial constraints. The recent incident has brought into question many of the assumptions that underlie the monitoring program.

IV. CONSTRUCTING SOLUTIONS

Finding solutions for the problems unearthed during the investigation depends upon an adequate statement of our objectives. To be precise, we must ask the question: What do we want our residue program to accomplish? The current USDA residue monitoring program does not and was not designed to ensure that all meat and poultry products in interstate commerce would be free from chemical residues. Neither does it ensure that a particular chemical accident will be discovered within any specified period of time. The program also does not tell producers or our own people with any great specificity how to handle problems once they have emerged, i.e., how to clean up problems with great efficiency. At present, the program meets only the following objective: It ensures, with a 95 percent degree of certainty, detection at some time during the year of any contamination that involves at least one-percent of the meat and poultry supply, provided that tests are available for the substance involved in the contamination. To put it bluntly, it is a horse and buggy solution for a jet age problem. That is not the fault of the program. The people now working in the residue program are are doing the best they can with current resources.

The costs of the current PCB contamination and the perception that the nation is on the upward slope of greater residue and contamination problems probably requires a restatement of the program's objectives. It needs to move away from being exclusively a monitoring program and toward a program that can provide a somewhat greater degree of

certainty in finding contamination, reducing the response time, and ensuring that more effective regulatory action is taken. The extent to which the current objective can be effectively changed flows from three factors: (1) the inherent limitations of sampling; (2) the state of the art in residue monitoring; and (3) the extent of financial resources available. The level of resources invested is currently a function of the state of analytic art and the sampling plans currently chosen. Any change in either of these latter two factors could result in a substantial change in the level of resources invested. The USDA is now studying each of these areas intensively. The state of the art of analytic sampling appears to hold long-term promise. In the meantime, a vigorous examination of the statistical underpinnings of the program is also underway. It is fair to assume that USDA is attempting to move the National Residue Program in the direction of becoming more regulatory in nature.

Regardless of any change in the overall design of the residue program, there are certain improvements the agency can make, or begin to make, immediately. Many of these improvements should be made for their own sake, and all of them can be considered prerequisites to a change in the overall focus of the residue program. These improvements will be discussed in terms of the five categories presented at the end of Part III (Public Awareness; Management-Procedural; Regulatory, Legislative, and Budget-Conceptual). The Budget-Conceptual portion will also include a brief discussion of how the National Residue Program might be moved in a new direction.

A. Education-Public Awareness.

The immediate problem for FSQS is to make its own employees more aware of the Agency's regulatory responsibilities for PCB and other environmental contaminants. Even at the height of the recent crisis, people within the Agency were expressing skepticism, at times publicly, about the seriousness of the contamination. Several factors contribute to this skepticism and make it difficult to overcome: the comparatively recent origin of residue problems; the invisibility of residues (as compared to, for example, diseased meat); their irregular occurence (unlike the daily need to keep food processing machinery clean), and the absence of any immediately discernable health effects.

There are time-honored ways for a government agency to educate its employees. It can send out directives and new instructions, change its training manuals and make "structural" changes. Such measures should not be ignored, and some of them will be discussed below under "Procedural-Management." The problem of environmental contamination is serious enough, and skepticism concerning it appears widespread enough, that unusual measures are called for.

As the first thrust directed at both employees and the general public, the Agency will attempt to capitalize on the interest generated by the recent incident. Despite all the attendant confusion, the incident has created an interest that can be turned to an educational purpose. The Agency has already been able to use the September 28 Congressional

hearing to good advantage. Videotapes of that hearing have been shown at several employee meetings in different parts of the country. The drama that such a hearing can have--kleig lights, the sharp exchanges--has helped bring home to employees the degree of concern over PCB contamination.

In the near future, the Agency will take further steps designed to build public awareness, as well as sensitivity within the Agency. There will be a series of seminars to discuss this report and obtain ideas on how best to solve the problems that have been raised. Initially, the seminars will include mostly Agency employees. This idea rests on the assumption that if you go to people asking for their help, involve them in discussion, and listen to them, they will invest themselves in the final product. It is important that people view the problem of environmental contaminants not just in terms of their own particular responsibilities, but as problems facing the Agency as a whole. Rather than telling them their duties during a crisis, they will be asked, "What changes should we make?" or "What would you do in this situation if you were administrator?" The purpose of the effort is to build awareness by encouraging people to view problems in ways that are different from the narrow "bureaucratic" perspective.

While enlisting the help and support of employees in dealing with residue problems, the Agency must be able to communicate the fact that there is indeed a problem with substances such as PCB. Three themes will be stressed, with the recent incident providing the bulk of the evidence for two of them.

First, PCBs are dangerous to health. This may be the most difficult theme to communicate, since PCBs at lower levels present a long-term rather than an immediate risk. The 1978 Yusho incident provides the best direct evidence of the effect on humans. What is required, however, is a careful statement, written in plain English, explaining why animal tests are valid, how the effects of certain chemicals are cumulative, and why there is no safe level of exposure for many chemicals.

Second, PCBs spread very quickly and very far in the food chain. This point can be graphically illustrated using the recent incident, and will emphasize the need for early detection and quick response.

Third, the economic impact of PCB contamination is dramatic. This, too, can be readily demonstrated from the recent incident. The impact involves not only the large numbers of chickens and eggs that had to be destroyed, but also the delays at every point in the production and distribution chain, and the stigma attached to products by consumers that affects future market acceptability.

In addition to stressing these themes at the follow-up seminars, the Agency is now exploring other ways to present them to the general public. It is particularly important to explain the risks associated with PCBs and other environmental contaminants. The IRLG, whose membership includes FSQS, FDA, and EPA, as well as the Consumer Product Safety Commission, and the Occupational Safety and Health

Administration, has the organizational base to lead a coordinated public education effort on the risks associated with environmental contaminants. During the next year, the IRLG will mount a broad based effort to inform the public on such matters as the toxic substances most likely to occur in the immediate human environment, the risks of these substances, and what is being done to control them.

B. Procedural Management.

Procedural problems are closely related to the problems of awareness. It is not sufficient for members of the Agency simply to be aware of the importance of chemical contamination. They also must know what they are supposed to do about it. They must know their specific responsibilities for detecting residues, and for responding when contamination occurs. The review of the recent PCB incident has revealed that many people did not fully understand what they should do. Official procedures lacked sufficient clarity, responsibilities were ill-defined, and lines of authority blurred.

In her September 28 testimony, Assistant Secretary Foreman outlined a series of steps that FSQS was taking to tighten and clarify its procedures in the residue area. They were mainly designed to prevent delays in the future in processing samples and reporting results. Since these steps were taken, the Agency has undertaken a more comprehensive task. It has devised a new Contamination Response

System (CRS), which lays out in explicit, step-by-step fashion the responsibilities of each component of the Agency at each stage of a contamination incident. What follows is further detail of the administrative steps outlined by Assistant Secretary Foreman on September 28, and then a description of the new Contamination Response System.

(1) Administrative Steps. The first step is the designation of people throughout the organization as contact points for following residue problems. The need for clear, established contact points became apparent as FSQS attempted to marshal its resources in response to the recent contamination. At the most basic level, establishing contact points has solved the problem of whose number to call when contamination is first detected. But at another level, establishing contact points assigned responsibilities for keeping various programs informed and prepared on residue matters. FSQS is a large agency--more than 11,000 people--with diverse responsibilities. While the day-to-day monitoring is largely the responsibility of the Residue Evaluation Staff, many different programs in the Agency become involved when contamination occurs. Since residues are not an ordinary responsibility of these programs, it is essential that one person bear the responsibility for keeping the program informed on residue matters, and prepared to respond.

The people who serve as contact points are also part of the Contamination Response Team, which will advise the Administrator

whenever concerted agency action against a residue problem becomes necessary. The Assistant Deputy Administrator for Field Operations, MPI, is Chairman of the Contamination Response Team. The conditions that will trigger concerted agency action and activation of this team will be discussed below.

The second, third, and fourth steps concern the FSQS Poultry and Dairy Quality Division. Prior to the formation of FSQS in March 1977, the Residue Evaluation Staff reported directly to the officials responsible for meat and poultry inspection. They had not worked closely with the officials responsible for egg products inspection, mainly because this responsibility was carried out in another agency within the Department. During the early stages of the recent contamination incident, there was poor communication between the Poultry and Dairy Quality Division and the other components of FSQS, including the Residue Evaluation Staff. In the meantime, the following steps have been taken to integrate the Poultry and Dairy Quality Division into the overall FSQS residue effort:

--Each regional office in the Poultry and Dairy Quality Division has been sent written instructions concerning the need for immediate action to communicate with appropriate officials when potentially contaminated product is found. A copy of these instructions is attached (Attachment 16).

--Poultry and Dairy Quality Division's Headquarters Staff has transmitted to the PDQ laboratory in Gastonia, North Carolina, procedures designed to assure that false negatives are not reported. (Had it not been for the report on a false negative at the Gastonia laboratory back in early August, the recent PCB contamination may have been discovered earlier.) To make certain that these procedures are being properly followed, FSQS detailed a member of the PDQ National Staff and a senior analytical chemist from the Science Division to Gastonia to work with personnel at that laboratory. These people also reviewed the records at the Gastonia laboratory over the past several months and conducted duplicate analyses on several samples from the past month to find out if there are other problems we have not known about. The review revealed no substantive problems. PDQ is now studying the feasibility of introducing new equipment at Gastonia which will automate the initial identification of the more common PCB residues. Even though equipment failure was not a problem at Gastonia, automation will lessen the chance of future human error.

--The Poultry and Dairy Quality Division has been identified as a party to the FSQS Memoranda of Understanding with the Food and Drug Administration and the Environmental Protection Agency. (Attachment 17.)

The fifth step concerns the Meat and Poultry Inspection Program's instructions on residues. Assistant Secretary Foreman stated in her September 28 testimony that these instructions had been reviewed, and weaknesses identified. The basic instructions on residues are found in MPI Directive 917.1, MPI Bulletin 77-114, the Meat and Poultry Inspection Manual, and a packet of information on residues that has been sent to the region. There are essentially two problems with these instructions: they are not always clear and they cannot be found in a single document.

In reviewing the record of the FSQS response to the recent PCB contamination, it becomes apparent that while most field personnel had a general notion of their responsibilities with respect to residues, they rarely made explicit reference to the basic instructions. MPI Headquarters staff has allowed the basic instructions to evolve over the years, and has not attempted to formulate them in a clear, comprehensive, and readily accessible fashion. Often the instructions assume too much knowledge. The instructions are now being rewritten to provide field personnel with a clear, unified set of instructions. They will include explicit procedures and timetables to be followed on sending samples to laboratories, reporting violative samples, and informing headquarters staff on residue related actions taken in the field. Pending revision of the MPI basic instructions, an Interim bulletin has been issued informing inspectors-in-charge that all samples should be submitted for analysis promptly after freezing. (Attachment 18.)

The sixth step is a new reporting procedure to assure that line supervisors in Washington are notified of violative residue findings in a timely manner. These new reporting procedures will be part of the Contamination Response System, which is described below in some detail. This system sets specific response levels for each of the environmental contaminants. A finding at a particular residue level will trigger a well-defined and predetermined set of actions from the field and headquarters personnel responsible for dealing with residues. As an interim cross-check on the new system, all FSQS regional offices have been instructed to notify the Residue Evaluation Staff in Washington immediately by telephone whenever there is a violative test result of an environmental contaminant, such as PCB.

Finally, all regional directors for meat and poultry inspection have been notified that violative levels of environmental contaminants shall be given priority attention (Attachment 19). In discussing the problem of awareness with the agency (pp. 79-81), it was noted that extraordinary measures are required to increase the overall sensitivity to the seriousness of problems of environmental contamination. As such measures are explored, the agency is also relying on established channels and traditional means.

(2) Contamination Response System. Control of environmental contamination depends upon early recognition of the problem and an expeditious response. The record of FSQS actions in the recent PCB incident reveals that recognition of the problem could have come earlier

and that response to the problem could have been quicker. To improve recognition and response time, FSQS has made a number of significant adjustments in its residue program, and has established clearer, more explicit organizational links between the residue evaluation staff and the other staffs within FSQS. The new approach for dealing with environmental contaminants is called the Contamination Response System (CRS).

The Contamination Response System has four basic elements:

--First, it sets conditions that will trigger a prescribed set of FSQS actions designed to determine the extent of contamination, notify other Federal and State agencies, and, if necessary, control and eliminate the contamination. For some environmental contaminants such as PCB, a single residue finding at the lowest detectable level is the "condition" that will set into motion a chain of closely linked actions.

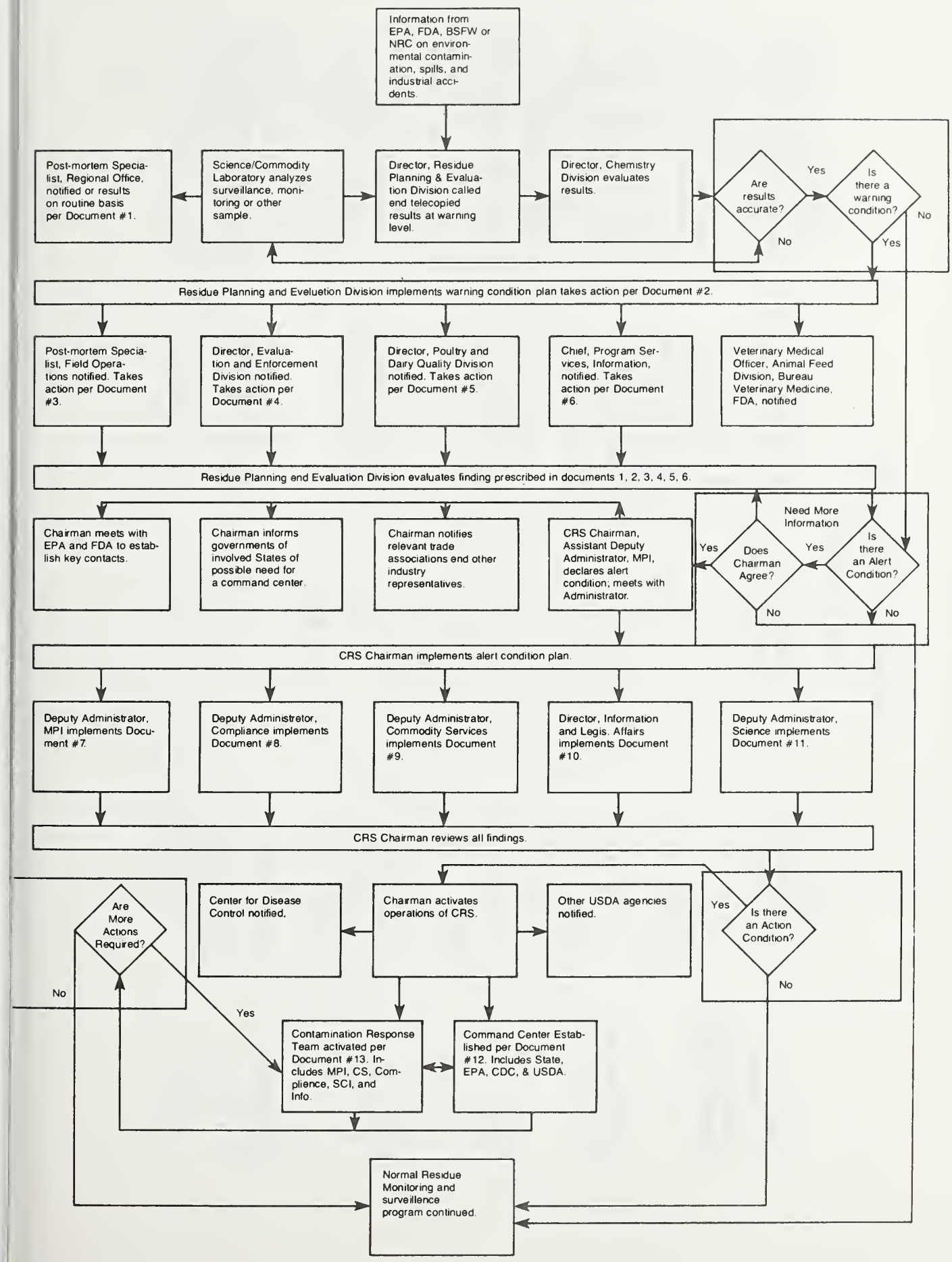
--Second, the response system lays out in systematic, step-by-step fashion the process by which FSQS will proceed from the initial detection of an environmental contaminant to a full mobilization to control and eliminate it.

--Third, the response system lists the specific responsibilities of each FSQS component (e.g., Compliance, Science, MPI Field Operations, etc.) at each stage of the process.

--Finally, the response system provides for activation of an agency-wide Contamination Response Team reporting to the Administrator whenever mobilization to control and eliminate contamination of the food supply becomes necessary. The Response Team will consist of the people who already have been designated as "contact points" for keeping their units informed and prepared on residue matters on a regular basis.

The following tables, flow chart, and list of responsibilities provides further detail on the Contamination Response System.

Contamination Response System



CONTAMINATION RESPONSE SYSTEM

Response Conditions

Compound	Tolerance or Action Level	Warning Condition	Alert Condition	Action Condition
Polychlorinated biphenyls (PCB)	in fat 3.0 in whole eggs 0.3	*	Any detectable level in a single sample (0.5 in fat and 0.05 in whole eggs)	Definite information indicating contamination of food chain in more than one location or management system
Polybrominated biphenyls (PBB)	in fat 0.3 in whole eggs 0.05	*	Any detectable level in a single sample (0.1 in fat)	Definift information indicating contamination of food chain in more than one location or management system
Kepone	in fat -- in whole eggs --	* *	Any detectable level in a single sample (9.1 in fat)	Definite information indicating contamination of food chain on more than one location or management system
Aldrin	in fat 0.3 in whole eggs 0.03	0.1 0.02	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
Benzene Hexa-cloride	in fat 0.3 in whole eggs 0.5	.20 0.3	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location

Compound	Tolerance or Action Level	Warning Condition	Alert Condition	Action Condition
Chlordane	in fat 0.3	.20	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs --			
Dieldrin	in fat 0.3	.20	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs 0.03	0.02		
DDT	in fat 5.0	3.0	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs 1.5	1.0		
Endrin	in fat 0.3	.20	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs 0.3	.02		
Heptachlor	in fat 0.3	.20	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs 0.3	.02		

Compound	Tolerance or Action Level	Warning Condition	Alert Condition	Action Condition
Lindane	in fat 4.0	1.0	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs 0.5	.2		
Methoxychlor	in fat 3.0	3.0	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
Toxaphene	in fat 3.0	7.0	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
Hexachloro-benzene	in fat 0.5	0.3	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
	in whole eggs	.2		
Mirex	in fat 0.1	0.1	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location

Compound	Tolerance or Action Level	Warning Condition	Alert Condition	Action Condition
Any Organic Phosphate	0.0 - 4.0 depending on compound	0.2 (Judgment used depending on compound)	Cluster of samples exceeding warning condition level	Cluster of samples and information indicating contamination of food chain at more than one location
Mercury	None established	0.5	Cluster of samples exceeding warning condition level	Information indicating contamination of food chain
Lead	None established	4.0 (Kidney or liver)	Cluster of samples exceeding warning condition level	Information indicating contamination of food chain
Cadmium	None established	4.0 (Kidney)	Cluster of samples exceeding warning condition level	Information indicating contamination of food chain

EARLY WARNING CONDITION

Documents 1-6

Document 1

Field Operations (Regional Office) Response to Warning Condition

1. Notify owner or producer by telephone. Obtain information on the cause of the residue.

2. Notify the plant where the sample was collected. If the result was violative retain any related product.

3. Prepare case file according to "Residue Program Guidelines for Region." Send a copy to FDA and State as designated.

4. Arrange for surveillance sampling if needed.

5. Telephone Regional FDA and request information on other products (feed or foods) recently found in area with the same residue.

6. Respond to information requests from PDQ related to warning condition in eggs or egg products.

7. Prepare for possible surveys and correlate with RES.

8. Report all information and findings to RES.

Document 2 - RES Response to Warning Condition

1. Notify Field Operations (Washington) of Warning Condition.

2. Notify Evaluation and Enforcement Division.

3. Notify Poultry and Dairy Quality Division.

4. Notify Information and Legislative Affairs.

5. Inform FDA (Washington) per Memorandum of Understanding.

6. Review all residue data for potentially related findings.

7. Evaluate and summarize information reported from all staffs. Determine what condition exists and report to Chairman of Contamination Reponse System Team.

Document 3 - Field Operations (Washington) Response to Warning Condition

1. Communicate the findings from Chemistry Division review to Field Operations regional office if results are contrary to those previously reported.

2. Alert regional office of Warning Condition.

3. Oversee activities of field.

4. Report information to RES.

Document 4 - Compliance Response to Warning Condition

1. Notify field officer(s) in appropriate region of a potential residue problem.

Document 5 - PDQ Response to Warning Condition

1. If initiating sample was from fowl, obtain name and address of owner from MPI. Determine if egg and/or ova from viscera of slaughtered fowl are involved.

2. If initiating sample was eggs, test related product to determine compliance.

3. Report information and results to RES.

Document 6 - Information Response to Warning Condition

1. Alert Area Information Offices.

ALERT CONDITION

Documents 7-11

Document 7 - Field Operations Response to Alert Condition

1. Notify all regions of Alert Condition.

2. Execute surveys developed for appropriate species.

3. Coordinate transmitting information in product contamination from FDA investigations to Compliance and PDQ as appropriate.

4. Prepare for investigational testing of involved farms.

5. Maintain contact with State and prepare for cooperative action.

6. Retain all violative meat and poultry products or carcasses.

7. Inform compliance and PDQ of all violations and names and addresses of owners.

8. Phone all information to Washington Staff to inform Deputy Administrator.

Document 8 - Compliance Response to Alert Condition

1. Obtain samples from distribution channels, to determine if product is violative.

2. Review all plant records pertaining to shipments of contaminated products.

3. Place additional compliance personnel on standby to assist in affected area(s).

4. If violative product is reported, coordinate voluntary recalls and execute detentions as necessary.

5. Maintain all records regarding reviews, persons contacted and product disposition.

6. Phone all information to the Enforcement Operations Branch, EED, Compliance Program to inform Deputy Administrator.

Document 9 - Commodity Services Response to Alert Condition

1. If ova and/or eggs are involved, determine the product location and test the potentially contaminated product.

2. Determine the movement of shell eggs from suspected flocks and identifying egg products plants receiving these eggs.

3. Advise involved egg products plants of potential contamination.

4. Test egg products manufactured from potentially contaminated eggs.

5. Retain contaminated products in plants. Request involved plants to voluntarily recall any such product located outside the official plant.

6. In cooperation with Compliance, request voluntary recall of product located outside official plants and retain any potentially contaminated product.

7. Assure proper disposition of all product involved in the contamination incident.

8. Phone all information to PDQ Division to inform Deputy Administrator.

Document 10 - Information Response to Alert Condition

1. Begin gathering information for any necessary press releases.

2. Respond to Press Inquiries.

3. Prepare briefings for USDA officials who take trips to affected areas.

4. Be prepared to send representatives to Command Center to answer press inquiries and coordinate media activities.

5. Issue any press releases necessary.

Document 11 - Science Response to Alert Condition

1. Develop survey of appropriate species.

2. Provide adequate laboratory capacity for survey samples.

3. Send epidemiologist to field to participate in epidemiologic investigation to define source and extent of problem.

4. Prepare factsheet on environmental assessment of compound.

5. Standardize method in all laboratories.

6. Prepare for expanded laboratory capability if action condition is declared.

7. Arrange for shipping containers and instructions.

8. Develop guidelines for collecting, compositing, screening and confirmation of samples.

ACTION CONDITION

Documents 12-13

Document 12 - Command Center Response to Action Condition

1. Continue epidemiologic investigation to determine source and extent of contamination if necessary.

2. Determine appropriate sampling techniques to establish compliance of involved farms.

3. Carry out farm testing and sample collection.

4. Communicate results of tests to producers.

5. Arrange for disposal of contaminated product.

6. Handle local public inquiries and disseminate information to the press.

7. Locate and maintain control over all contaminated product.

8. Provide producers with information on metabolism of contaminant.

9. Determine necessity of testing non-associated farms.

10. Keep Task Force informed of progress and additional activities or resources needed.

Document 13 - Task Force Response to Action Condition

1. Coordinate FSQS Activities to provide support for Command Center.

   This may include:

   (a) Laboratory facilities.
   (b) Scientific information on metabolism of compound, safety and tolerance.
   (c) Additional field personnel.

2. Address legal questions and congressional inquiries that arise.

3. Keep Administrator informed of situation and the progress.

4. Coordinate activities between FSQS, EPA, FDA Washington Staff.

5. Inform Command Center of any policy changes.

In the future, the contamination response system should help avert many of the difficulties that surfaced in the recent incident. It addresses, for example, the awareness problem within the Agency. The very existence of a plan, the training accompanying it, and its linkage to Headquarters Staff should heighten the sensitivity of FSQS staff to the problems of PCB contamination, and enable the Agency to respond to incidents in an organized fashion. It should also improve the coordination of sampling. In the early stages of contamination, the command center is directed to "determine appropriate sampling techniques and carry out farm testing and sample collections." It should also help to prevent backlogs. When the alert condition occurs, the Science staff is directed to prepare immediately for expanded laboratory capability, arrange for shipping containers and instructions, and develop guidelines for collecting, compositing, screening and confirming of samples. In sum, the Contamination Response System will impart a sense of urgency to problems of environmental contamination, and will provide an integrated, systematic agency response to such problems.

C. Regulatory.

As Chairman Eckhardt stated at the September 28 hearing, the most alarming aspect of the recent PCB contamination may be the fact that there is still a large amount of PCB present in transformers and other industrial equipment throughout the country. Over the past 2 months, FSQS officials have been meeting with representatives of FDA and EPA

to develop a joint regulatory approach for phasing out PCB. There are a number of difficult questions still to be resolved. These include: the technological feasibility of removing all PCB from existing equipment (should very low levels be permitted, and if so, what exactly should the upper limit be); the means for disposing of PCB once it has been removed from equipment, and the availability and safety of alternatives to PCB.

As a preliminary step to an eventual phaseout of PCB, FSQS has asked the inspectors-in-charge at meat and poultry plants to alert plant management of the potential danger of PCB, and to make an inventory at these plants of all equipment containing PCB (Attachment 20). For some time, FSQS has required the submittal of formulations for hydraulic fluids, greases, and oils used in official establishments, and does not approve any that contain PCB. This review and approval process does not apply to fluid used in transformers and capacitors.

The inventory of equipment containing PCB is the first step in a plan to phase out the use of PCB in all places where the Agency has inspection or grading authority. The next step will be a final regulation, to be issued within the next month, to prohibit the introduction of any new equipment containing PCB into meat and poultry plants. The final step, which will be carefully coordinated with EPA and FDA, will be a regulation requiring the removal and disposal of all PCB in existing equipment. FSQS believes it will be able to resolve the remaining questions and publish this proposed regulation within the next 3 to 4 months.

D. Legislative.

The accounts of the detection of the recent PCB contamination and the clean-up effort that followed present a compelling case for two new types of Federal authority. The first is the authority to quarantine livestock and poultry when there is reason to believe they contain unlawful residues. The second is the authority to require that all livestock presented for slaughter be identified in a way that previous ownership can be determined.

The need for quarantine authority became particularly clear during the clean-up effort in the State of Montana. In the absence of authority to hold suspected animals on farms or in feed lots, FSQS was forced to rely entirely on hold and test restrictions at the Federal plants. The result was a quick back up at the plants, and the loss of any semblance of orderly distribution. Had a quarantine been invoked at locations where contamination was suspected, the producers of non-violative animals would have incurred much lower costs, and the Agency would have been in a position to employ selective sampling rather than employ the shotgun approach. There also would have been far greater assurance that consumers were being protected.

Identification authority can also save time in determining the cause of original contamination. In fact, for red meat animals that often pass through several owners before slaughter, animal identification is the only sure method of tracing an animal back to the source of

contamination. The need for identification can be dramatically illustrated by considering what would have happened in this incident had the slaughter plant where the violative sample was taken not kept a record of the origin of the contaminated animal. Companies are not required to keep such records, and many of them do not. As a result, there have been instances in the past where the effort to trace the source of contamination has reached a dead end at the slaughter plant.

To close off gaps in the present Federal authority to deal with residue problems, FSQS has developed a legislative proposal that would provide specific authority to quarantine and require animal identification. According to this proposal, livestock and poultry under quarantine would not be permitted to move until the quarantine order is revoked. The cost of any testing to determine that unlawful residues are no longer present would be borne by the owner of the livestock or poultry. The proposal provides for expedited appeals of quarantine orders, but such orders remain in effect pending the outcome of appeals. This amendment also would require all livestock presented for slaughter at official establishments to be identified in a manner so that ownership for the previous 90 days can be determined. The type of identification would be left to the discretion of the packers and producers.

These proposed changes in the Federal Meat Inspection Act and the Poultry Products Inspection Act are in line with the recommendations made by the General Accounting Office in their 1979 report, Problems in

Preventing the Marketing of Raw Meat and Poultry Containing Harmful Residues. GAO recommended "that the Congress amend the Federal Meat Inspection Act to authorize Agriculture to 1) quarantine animals from violative growers and 2) require growers to place an identification tag on animals before they are marked."

In developing this legislative proposal, FSQS explored several different alternatives, including a major expansion of residue testing activities and a stepped up enforcement program relying on civil penalties. An analysis of the alternatives revealed that the use of new quarantine and animal identification authority would be the most cost effective means of dealing with the problem of residue violations. An expanded testing program, for example, would be far costlier to the Federal Government, and greater reliance on civil penalties alone would not deal with the problem in a direct, effective fashion. The analysis comparing the various alternatives is attached (Attachment 21).

E. Budget-Conceptual.

The western PCB spill, affecting commodities distributed over a wide geographic area, clearly illustrates the vulnerability of this nation's complex food chain to chemical contamination. Beyond exposing the management and programmatic problems of USDA's residue monitoring system, the recent accident challenges the very assumptions of that program. Even if the program worked as designed with no human errors or communication problems, it could still not guarantee a food

supply free of chemical residues. Given the health threat associated with such contaminants and the magnitude of the exposure due to the nature of the food chain, it is important that USDA broadly examine its role in assuring food safety. The PCB incident has demonstrated risks previously only hypothesized, and has generated a public concern that makes a greater commitment to residue monitoring more feasible.

The USDA residue monitoring program does not and was not designed to certify meat, poultry and egg products free from chemical residues. Rather, it is a system based on sampling techniques to detect "some" residues with "reasonable" accuracy, and, if they are identified, to stop their spread throughout the food chain. This distinction between certification and monitoring is significant and fundamental to the PCB accident. Each product is not tested individually for residues; the random sampling techniques only provide a level of certainty that relates to the entire food supply for a period of a year. It is conceivable that residues could contaminate food and not be detected.

The recent PCB spill, for example, was originally detected from samples taken at the Jolly Wholesale Poultry plant in Provo, Utah. This plant, due to its relatively low volume of production in relationship to national patterns, is only sampled once a year. The fact that the PCB appeared during this one test is fortuitous; had the inspection taken place a month earlier, there would have been no detection of contaminated poultry, and therefore, no reason to believe that a spill had or would occur. At other points within the food chain, other samples might have

been taken by USDA, FDA or private industry which could have identified contaminants had the Jolly sample not been taken. The further the contaminant is detected from the source of the spill, however, the greater the likelihood of contaminant spread throughout the food chain. Furthermore, there is the greater difficulty in tracing the spill to the source and containing the spread.

A further problem with the residue monitoring system in general becomes apparent when PCB is viewed as only one of a host of chemicals that can enter the food system. While PCBs enter the food chain by accident, the inadvertent mechanical error, other chemicals are routinely injected into animals or used as fertilizers to stimulate growth and limit disease. USDA's maximum response to such potential contamination is random sampling designed to identify residues that were not previously eliminated from the product. But perhaps more importantly, of the 140 chemicals that are regularly used with food production, USDA has the technical capability of only identifying 43 through laboratory testing. Clearly, each of these potential contaminants are not as potentially toxic as PCBs; nonetheless, tolerances for these chemicals cannot even be policed at this time, due to limits in the state of the art.

USDA has attempted to maximize the protection it can afford consumers given limitations of budget and technology. As previously discussed, the management and internal workings of the existing program are now being re-evaluated and changes made in light of the recent PCB spill.

The larger question though, relates to the goals and limitations of the entire program, to the "level of effort" associated with residue control. What policy options are available to assure a greater degree of product safety with respect to contaminants and at what cost?

The options now being considered by the Agency as part of a re-evaluation of the residue program fall roughly into five categories: (1) increased sampling; (2) expanded research in new detection technology; (3) a broadened information base; (4) increased reliance on private sampling, and (5) earlier sampling. In the aftermath of the recent PCB incident, it is clear that there are choices in each of these areas, whether considered separately or in combination, that will increase the effectiveness of the residue program. Many of these steps will require additional funds, at least in the short-run. However, the options being considered do not merely represent the addition of resources, but also involve changes in the present design of the residue effort.

(1) Increased sampling. Testing every animal for chemical residues is clearly an unrealistic option. Costs would be prohibitive, exceeding an estimated $50 billion in red meat animals alone. Therefore, recommendations in the past for increasing the effectiveness of the residue program have focused simply on an increase in the sampling effort. For example, the report of the House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations on "Cancer-Causing Chemicals in Food" states: "USDA's

random sampling monitoring program should test more animals for chemical residues. Testing only 1 in 3,000 livestock and 1 in 700,000 poultry does not afford a true picture of the extent and nature of chemical contaminants in meat and poultry."

Up until now, when the Agency has considered major expansions in its residue effort, these considerations have quickly run up against budget limitations. A recent Agency study estimated that it would cost $92 million to increase monitoring by 20 times the present rate, expand laboratory facilities to accommodate increased sampling, and extend the use of rapid test techniques. This option appears unrealistic when viewed against the present FSQS budget of $280 million, but may turn out to be cost-effective when viewed from the perspective of the total government-wide budget for controlling toxic substances, and the government and private costs associated with a contamination incident.

The Agency is now developing a precise set of budgetary options based on increased sampling. The present monitoring effort provides 95 percent assurance that over the course of a year it will catch any contamination that involves more than one percent of the nation's meat and poultry supply. Even if it is impossible to catch all contamination, this would appear to be rather loose coverage. The question is "What would it cost to provide X coverage and what would it cost to provide Y coverage?" The Agency is now reexamining the statistical basis of the present monitoring program to see how the net might be tightened through increased sampling.

(2) Detection technology. The most significant gaps in the present residue program clearly result from a lack of technology. First, there are no tests available to detect most of the chemical residues that may be present in food. Second, even the tests available are expensive and time consuming. Clearly, research and development to devise new tests for regulatory purposes must continue. While there has been some recent progress in this area (FSQS is now employing a rapid screening test for antibiotics in cull dairy cows), the present technological limitations are not likely to be overcome in the near future. The Agency, however, does face some immediate policy choices, centering on the question: given the present level of public concern over residues, are sufficient resources being devoted to the development of new testing techniques? FSQS recognizes that it is not alone in this effort, and is attempting to channel and utilize the resources available in other agencies, in the private sector, and in academe. It is an effort that will require constant oversight and frequent reevaluation.

(3) The information base. The present FSQS National Monitoring program relies upon random sampling and the use of statistics to obtain an accurate picture of the incidence of chemical residues in meat and poultry over the course of a year. Its main purpose is to inform the agency on long-term trends and not to detect particular contamination incidents promptly so that the Agency can take action to limit the extent of the contamination. One of the questions posed by the recent PCB contamination in the west is whether the focus of the program

should be changed to provide greater likelihood that particular incidents will be detected.

As discussed above, the most straightforward way to expand "coverage" is to increase the number of random samples. This might be accomplished while leaving the present framework of the monitoring program intact. Another means of expanding coverage, however, would be to abandon the random, nationwide design of the present program, and instead concentrate sampling in those places where violations are most likely to occur, and where samples will obtain the maximum amount of information.

This new design would depend upon an expansion of the information base to include more information on the patterns of agricultural use of chemicals, the history of past incidents, distribution patterns for animals, and distribution patterns for feed. The present monitoring system assumes a stance of statistical neutrality to this type of information, and relies mainly upon an information base of the samples themselves. By including more information, the focus of the program would change from one whose main purpose is an accurate statistical picture, to one whose purpose is to maximize the chances of detecting the greatest number of single incidents.

Such a change in focus raises the question of whether the monitoring effort should be directed more to some types of chemicals than others. For example, in view of the recent PCB incident, and the series of

similar incidents over the past 10 years, should FSQS direct its monitoring efforts more in the direction of environmental contaminants, which occur by accident, and away from animal drugs, whose use can be controlled? Or, should the monitoring effort be based on a ranking of chemicals by public health significance? These and other questions are now under intensive review as FSQS attempts to design a program that will provide a greater degree of protection.

(4) Private monitoring. In the past several years, a number of large integrated poultry concerns and a number of food processing firms, such as Swift and Campbell, have begun to test their own products for chemical residues. In fact, the residue testing program at a Campbell's plant in Iowa was instrumental in tracking contaminated poultry during the recent incident. While FSQS has been aware of these programs and has on occasion been able to use them in tracking contaminated product, it has not actively encouraged the development of such private testing capacity, and has made no attempt to utilize it in any systematic fashion.

The residue testing now being conducted privately can play an important part in the FSQS effort to extend the coverage of its own monitoring efforts. In the simplest terms, one sample taken and tested by a private firm is one that the Agency does not have to take, and resources are freed that can be directed elsewhere. In order to rely on private sampling and to make it a part of the overall monitoring effort, however, the agency will need to develop a set of guidelines and

agreements for the firms involved, and employ a system of regular checks. Given the tremendous costs that can be associated with contamination, it is clear that many firms will have a clear economic incentive in instituting government approved testing programs. Such programs may also provide impetus in the development of faster, more inexpensive testing techniques.

(5) Early monitoring and sampling. There are obvious advantages to sample testing at the earliest possible point in the food chain. To the extent that contamination does occur at these points, the risk of spread can be minimized. To the extent that the contamination occurs at a lower point in the chain, its source can be more easily identified.

In the most recent PCB spill, and in previous spills, contamination occurred at the feed production level. There is an obvious need for expansion in the feed testing area. This is currently an area of exclusive FDA jurisdiction, but as FDA enlarges its feed testing program, FSQS must work closely with FDA to see that this effort is coordinated with the overall monitoring program.

The recent cleanup effort has also clearly demonstrated the usefulness of sampling at the farm or feedlot. During the recent incident, the vast majority of the samples were taken at federally inspected plants. Samples taken at plants, however, yield only a limited amount of information. When the test on the sample reveals an illegal residue, it is often possible to check plant records to find the farm or feedlot

where the contaminated animal originated. Frequently, however, the animal may have been fed at several different locations. It requires a major investigative effort to determine exactly where it received contaminated feed, and then to determine where that feed came from and how it became contaminated. A sample taken on a farm or feedlot is often far more useful in locating the source of the contamination. Information on an animals feeding history, including the specific feed used, can be recorded at the time the sample is taken. Then, in instances where the sample proves violative, the search for the source of contamination has already been narrowed considerably.

The Agency will be exploring the expanded use of early sampling in both the monitoring and the surveillance phases of the National Residue Program. Early sampling can extend the monitoring coverage for environmental contaminants, particularly if the Agency can rely on feed sampling conducted by FDA at large feed distributors. During the surveillance phase, more sampling at the producer level will help prevent the flow of contaminated product while at the same time minimize disruption, inconvenience, and economic losses to producers. Although the Agency does not have authority to collect samples at the producers premises, the recent certification program in Montana shows that the Agency can work with State and local personnel in selecting animals from the farm to be sent to slaughterhouses, where they can be sampled and tested. Finally, the whole strategy for sampling during a crisis requires considerable forethought to develop contingency plans, guidelines and procedures.

F. The Future

The review of this PCB incident in the Western United States has obviously raised more questions than it has settled. This report, therefore, can by no means be considered the final word on this incident. In fact, the intensive review of the Agency's responsibilities and capabilities in the residue area has really just begun. However, the main outlines of how the Agency will proceed in the months ahead appear to have been established.

The need for further regulation of PCBs in the food plants is now clear. The agencies involved (FSQS, FDA, and EPA) should be ready with new regulations within 3-4 months. There also appears to be a compelling case for new legislation to provide the Agency with quarantine authority and the authority to require animal identification. The Department should be able to submit such proposed legislation to the Congress within the next 2 months.

The Agency has already been able to make a number of significant changes in its procedures and the organization of its resources for responding to contamination incidents. However, the task in this area is also by no means completed. There are two overriding questions: first, are sufficient resources now being devoted to the control of chemicals, and second, how can the National Residue Program be redesigned to assure greater likelihood of detection, and more

effective response? The Agency must look outward to find answers to these questions, which will entail wide-ranging discussions with industry, consumers, other Federal agencies and the Congress in the months ahead.

ATTACHMENTS

UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Meat and Poultry Inspection Program
Washington, D.C. 20250

ATTACHMENT #1

ACTION BY: Regional Directors and Inspectors in Charge

INFORMATION FOR: Area and Circuit Supervisory Personnel, Plant Management, and Interested Parties

Meat and Poultry Residue Program

I PURPOSE

This program is designed to maintain vigilance for nonpermitted biological residues in food animals.

II OBJECTIVES

The Meat and Poultry Inspection Program's (MPI) objectives are to establish uniform procedures and guidelines for program employees to assure compliance with the regulations when residues are suspected or found in edible tissues of animals slaughtered for human food.

III DEFINITIONS

A Animal. Includes all livestock and poultry.

B Blanket Survey. Involves sampling two flocks per shift each day for 5 consecutive workdays in each plant of the integrated operation.

C Compliance. Any residue finding that is at or below the established tolerance or C action level. (See Exhibit F for tolerance and action levels.)

D Integrated Operation. Centralized control over feeding, medication, and slaughter of animals from several producers.

E Lot:

1 Producers. A group of livestock or poultry within a unit.

2 Comparable. Any group that is approximately the same size and age as previous lots shipped by the same producer.

DISTRIBUTION:	MANUAL MAINTENANCE INSTRUCTIONS:	OPI
A-O by IC P,Q,S,U,U-2 by AMCS	This directive deletes MPI Directives 917.1, Rev. 1, and 917.2, Rev. 1.	STS-ISR

3 Packers or Warehouse. Product identity based upon slaughter date or time, owner, weight range, storage location, etc.

F Official Sample. Any tissue prepared by or under supervision of an MPI official in accordance with official procedures.

G Pretest. A laboratory analysis of a representative sample from a lot of livestock or poultry taken before they are shipped to slaughter.

H Sample Set. All tissues required for a specific laboratory evaluation from one head of livestock or six heads of poultry. For example, liver, kidney, muscle, fat, and tissue from injection site are required for antibiotic analysis.

I Split Sample. An official sample, a portion of which is sent to an MPI laboratory, and the remainder to a recognized, private laboratory for the same analysis.

J Standby Sample. A portion of a sample identified and secured for future reference.

K Potential Violation. Any residue finding that is 80 to 100 percent of the established tolerance or guideline.

L Unit. A feedlot, barn, house, pen, or segment of a feedlot, etc., with its own feed and water and separated from other units by a barrier.

M Violation. A residue finding above the established tolerance or guideline.

IV SAMPLING

Tissue samples must be collected, prepared, and shipped as specified in this directive. Failure to do so will result in samples which are unacceptable to the laboratory. See Sampling Guide (Exhibit D) and packing instructions (Exhibits B and B-1).

A Monitoring Phase.

Tissue samples are randomly selected from carcasses of normal appearing animals for residue analysis. Results are used to predict trends, incidence, and provide information for compliance and control.

The Residue Evaluation and Planning Staff, Scientific Services, (STS-REP) formulates programs for use in Federal and State establishments related to various drugs and chemical compounds. The Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and other Federal Agencies provide counsel and guidance.

The regions will receive monthly, a list of sample plants, dates, species, tissues, labels, and request forms (MP Form 23-1) for Federal and State plants. Federal establishments will be listed on each form. State establishments will not. Caution: Form MP-23-1 (Exhibit A) is designed to be used in the monitoring phase programs developed by STS-REP. Only those changes indicated by this directive are to be made to the preprinted entries in this form. Improvisations, except for the collection date, will result in computer data tabulation error. The MP Form 23-1 is not to be used for purposes other than outlined herein.

1 Instructions for MP Form 23-1--Federal and State Plants (Exhibit A). The inspector in charge of a plant selected to collect a sample for residue analysis will receive an MP Form 23-1 and a label addressed to the laboratory which is to analyze the sample. The form consists of two sections--an identification and results section and a tear-off strip. Preprinted information provides sample collection instructions, establishments, species, tissues, date of sample collection, and receiving laboratory. These instructions will be implemented according to the following procedures and requirements:

a The information regarding sampling schedules must not be accessible to plant management. Laboratory results are to be made available to plant management.

b The inspector in charge at each plant is responsible for collecting the type sample on the date indicated.

c If the species requested is not slaughtered on the date scheduled for sampling, collect a sample on the first subsequent day this species is slaughtered not to exceed 7 calendar days for Federal plants or 14 calendar days for State plants. Write in the true collection date.

d If there is no slaughter of the specified species during the required time interval, write "No animal available for sampling" and reason across the front of the MP Form 23-1 and on the lower part of the tear-off strip. This information is needed for preparation of future sample programs.

e If a plant suspends slaughter of a species, write the reason and the estimated date slaughter will be resumed across the front of the form and on the lower part of the tear-off strip.

f Complete MP Form 23-1 (Exhibit A).

g Use an approved, insulated shipping container and a full complement of frozen coolant.

h Freeze samples prior to mailing. (See Exhibit B and Exhibit B-1 for packing instructions).

i Attach label to "airmail" side of mailing frank and insert in sampling mailing box window.

j Distribution instructions for MP Form 23-1 when sample is available:

(1) Tear off lower portion of MP Form 23-1.

(2) Place all copies of upper portion in shipping container.

(3) Wrap white tear strip around sample bag.

(4) Retain pink tear strip as evidence of sample collection.

(5) Mail yellow tear strip to the area office for control purposes.

k Distribution instructions for MP Form 23-1 when no sample is available:

(1) Federal plants. Follow normal distribution of the form, except keep the specimen box.

(2) State plants. The State inspector is to record the reason that no sample is available across the front of the form and on the tear-off strip. Return the MP Form 23-1 and the specimen box to the designated MPI office. This procedure is simplified by providing the MPI office address on the reverse side (regular mail) of the mailing frank. The MPI office verifies that the reason for noncollection is recorded on MP Form 23-1 and returns it to the STS-REP Staff, Washington, D.C. 20250.

2 Method of selecting State establishment.

a List establishments slaughtering the requested species in Column A.

b Number the plants consecutively in Column B.

c Let "N" equal the number of establishments listed and "S" equal the total number of residue sample requests for that species.

d Divide "N" by "S" $(\frac{N}{S})$. Remove all digits to right of decimal point and add "1" to determine the sampling interval.

e By blindly dropping a pointer, select a random number between "1" and "N" using the random number table (Exhibit C). This number will be the first sample plant drawn from Column B. Select additional plants systematically down the column at the sampling interval until the required number of selections are made. If the end of Column B is reached before "S" number of samples have been chosen, continue at the beginning of the column.

f Example:

Column A	Column B
43A	1
29	2
186	3
35BG	4
92	5
437	6

Example: You are requested to collect three calf samples; therefore, N = 6, S = 3, N/S + 1 = 3. A random number between 1 and 6 from the table of random numbers is 2. Collect a sample from plant 2. Since the sample interval is 3, count down Column B three plants and sample from plant 5. Count to the end of Column B and continue at the beginning of the column to choose number 2 for the third sample. The plants sampled are 29, 92, and 29.

3 Sample collection:

a Determine total hours for slaughter of the desired species or class and randomly select the hour for sample collection. Repeat random selection when more than one sample is to be collected.

b Select normal appearing tissue from "passed" carcasses.

B Surveillance Phase.

This phase is used to detect, study, and control specific chemical or drug pesticide residue problems in livestock and poultry.

1 Regional Responsibility:

a Initiate surveillance procedures, including notification of producers and State and Federal agencies, when violative and potentially violative, residues are found in meat and poultry. Telephone communication with a producer or integrated operator may be necessary to obtain history and explain followup plans.

b Use the sampling program described under Section V, Procedure B, for potentially violative residue findings.

c Use the sampling program described under Section V, Procedure C, for actual violations.

d Consult with STS-REP when these rules do not apply.

e Inform (1) livestock and poultry owners, (2) District Office of FDA, (3) STS-REP, (4) MPI area office, and (5) State officials of a tissue analysis which will require action altering future livestock and poultry shipments from premises of origin.

2 Inplant Inspection Responsibility:

a Ante-mortem. "Suspect" all animals in a producer's lot when signs of poisoning, drug, or pesticide treatment or unnatural behavior are observed. Obtain a history of previous treatment and movement from plant management. Examine all animals and only allow slaughter of those selected for post-mortem examination and sample collection for laboratory analysis. Consult with supervisor for guidance in preparing a sampling plan.

b Post-mortem. In addition to retentions called for in a above, retain all carcasses and their parts in a lot when lesions indicating poisoning, drug, or pesticide treatment are observed. Obtain a lot history and consult with supervisor for guidance in preparing a sampling plan..

c Complete MP Form 23 (Exhibit E) for all samples submitted.

V PROCEDURE UPON RECEIPT OF LABORATORY ANALYSIS

Apply the following procedure to laboratory findings from either the monitoring phase or first sampling of the surveillance phase initiated by field personnel.

A In Compliance--No action

B Potential Violation--Residues between 80 and 100 percent of the tolerance or action level.

1 Notify management, producer, or owner immediately by telephone and arrange for additional sampling. Confirm by letter--copy to STS-REP.

2 Sample the next lot of livestock or poultry as in 3 below. DO NOT RETAIN carcasses and edible products.

3 Sample rate. Collect as in sample guide below:

a Livestock. Each sample must contain tissues from individual carcass.

b Poultry. Each sample must contain tissues from six birds. Collect, in addition, a six-bird sample from each of five other producers in the integrated operation. Do not retain the birds.

4 Sample guide:

Lot Size	Sample Size: Poultry	Sample Size: Livestock
1 - 10	1	All
11 - 20	2	10
21 - 60	3	12
Over 60	5	15

C Violations.

1 Notify plant management, producer, or owner immediately by telephone of a violative residue finding and that compliance must be established under one of the options in 2 below, before future lots will be released for food. Confirm by letter--copy to STS-REP.

2 Producer options:

a Slaughter under retention until official tests demonstrate compliance.

b Ante-mortem retention until satisfactory results of the test lot are received.

c Pretest before shipment to establishment. However, inspector will always collect at least one sample when remaining animals are slaughtered.

3 If producer declines to designate an option the inspector will "U.S. Retain" future shipment and slaughter under retention until proven free of violative residues. Return the producer to regular slaughter procedures after the next "comparable lot" is found less than 80 percent of tolerance. This applies to any of the five producers in an integrated operation also.

4 Producers may use a "recognized laboratory" to expedite return to normal slaughter procedures. A "split sample" must be sent to MPI laboratory (Exhibits B or B-1 and E).

5 Sample guide: All Violations.

Lot Size	Sample Size: Poultry	Sample Size: Livestock
1 - 11	1	All
12 - 16	2	12
17 - 40	3	15
41 - 250	4	25
Over 250	5	30

Acting Deputy Administrator
Meat and Poultry Inspection Program

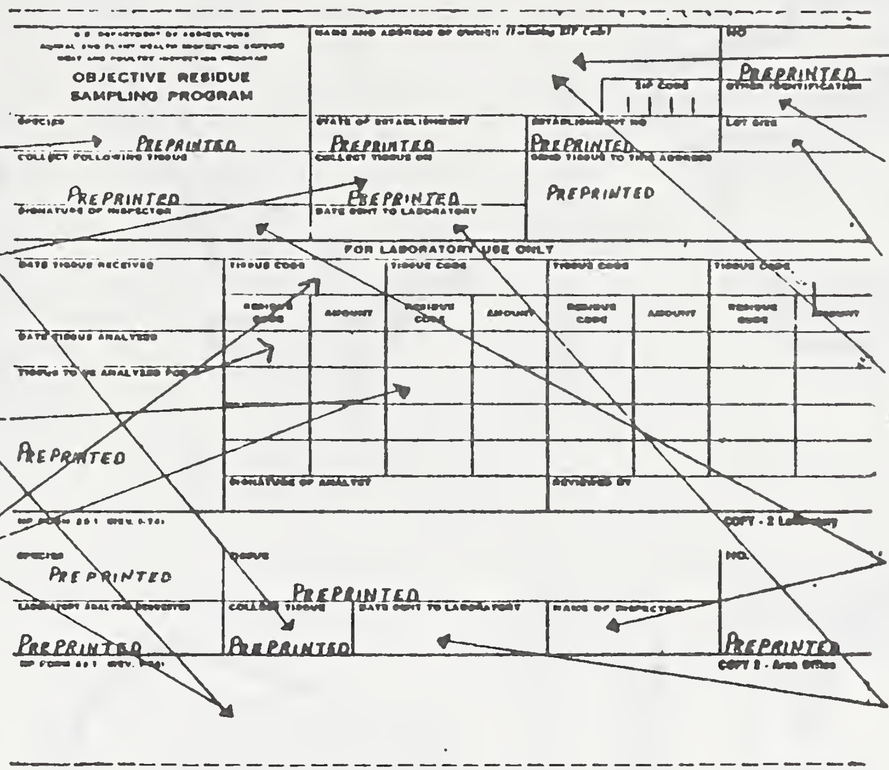
If the species requested is not slaughtered on date specified, collect sample on first subsequent day species is slaughtered not to exceed 7 days in Federal plants or 14 days in State plants.

Cross out preprinted date and write in true collection date. (NOTE: This is only preprinted matter inspector may alter.)

If no slaughter of requested species during required time interval, write "no animal available for sampling" and reason across the face of the form and lower part of tear strip; or,

If plant suspends slaughter of requested species, write the reason and estimated date slaughter will be resumed across the face of the form and lower part of tear strip.

See Exhibit G.



Full name and address (including zip code) of owner or producer.

Record back tag number, ear tag number, plant lot number, or any other identification. This information required even though owner's name and address is available.

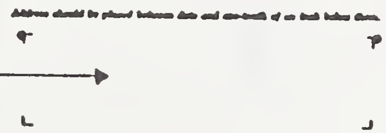
Refers to producer's lot size at farm, feed yard, or house.

If owner or producer identification or adequate traceback information is not available, samples must, nevertheless, be collected during the designated time interval. The Regional Office and Field Operations, Washington, D.C., shall be informed of the problem if a satisfactory solution cannot be obtained.

Inspector sign both places.

Date sent to laboratory. Fill in both places.

Plant mailing address (including zip code) of inspector submitting samples.

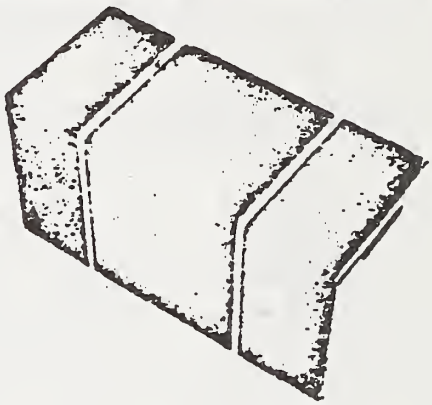


(REVERSE SIDE OF COPY 3 - INSPECTOR'S COPY)

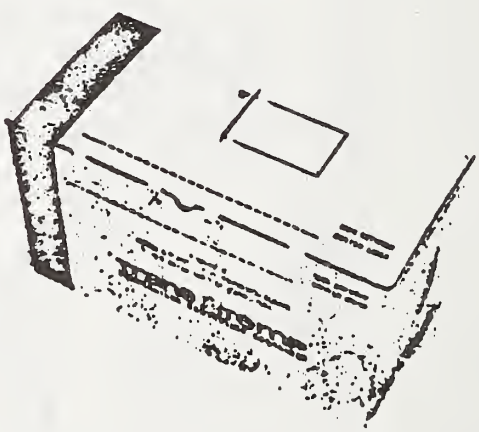
1. FREEZE CONTROLLANT CANISTERS IN ACCORDANCE WITH INSTRUCTIONS PRINTED ON CANISTER.
2. PLACE FROZEN CANISTERS INTO CONTAINER.

* 3. Place samples into freezer overnight.
* 4. Place container into freezer (open cover) and precondition overnight.

5. After freezing overnight, place sample in container. Place laboratory form (in plastic bag) between inner and outer lids.



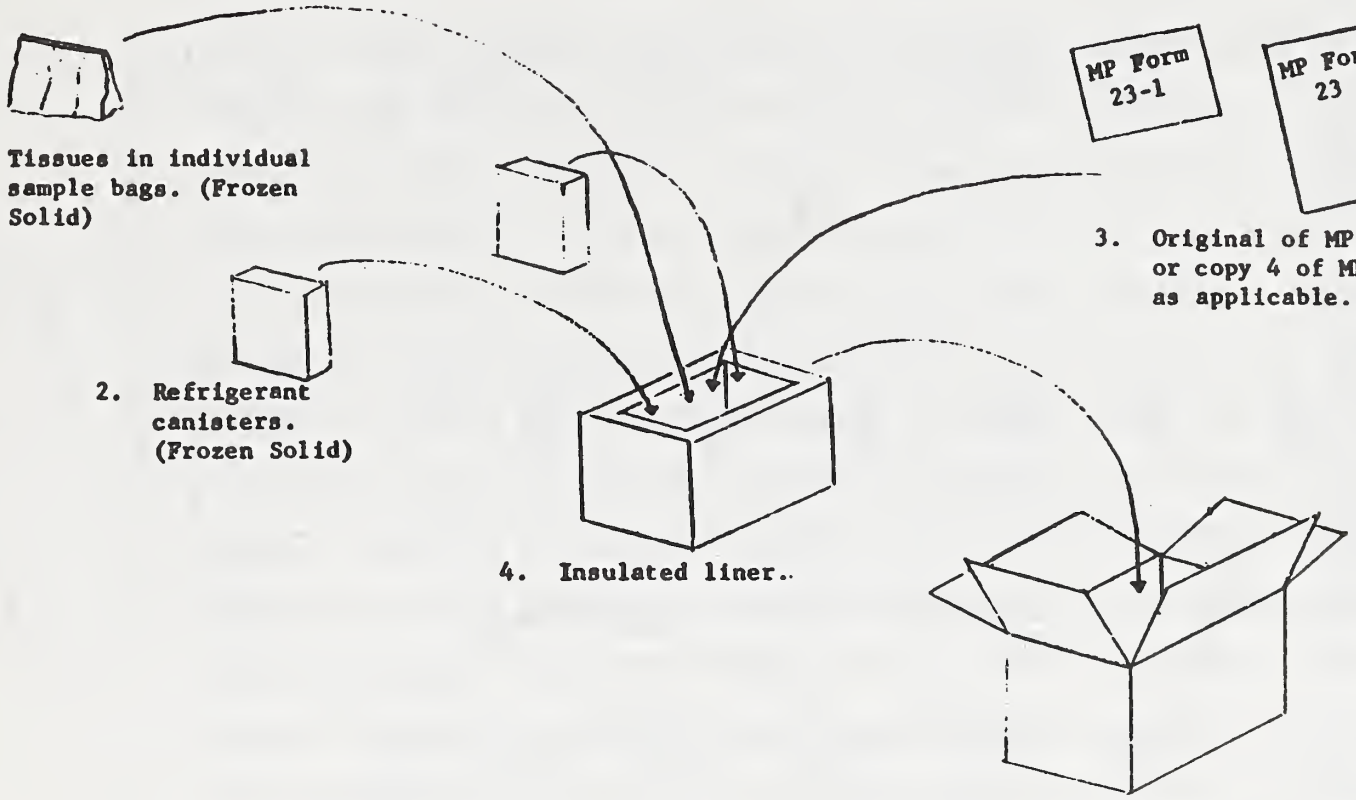
6. Close and secure box.



7. Refer to MPI Bulletin 76-51 Item 7 (Revised).

ATTENTION: IC and Regional Directors -- Reproduce and distribute according to indicated codes.

DISTRIBUTION:	SPECIAL INSTRUCTIONS: In MPI Directive 917.1, Rev. 2, delete Exhibit B, Keep Exhibit B-1, and insert this page	OPI: STS-IC
A-0 by IC P,Q,S,U,U-2		



PACKING INSTRUCTIONS

TABLE OF RANDOM NUMBERS

ROWS	COLUMNS 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	ROWS
1	289	130	667	693	268	218	373	252	632	689	705	973	158	15	584	1
2	750	472	291	137	649	591	694	485	54	481	95	801	25	208	488	2
3	467	193	545	686	16	741	11	98	135	12	434	542	998	351	451	3
4	472	5	149	647	316	388	186	729	953	881	589	638	783	68	486	4
5	654	587	693	141	718	442	62	976	352	782	943	116	685	162	59	5
6	357	452	513	863	355	816	889	538	382	518	315	167	959	728	234	6
7	658	18	638	812	75	675	65	447	478	890	387	946	250	151	465	7
8	117	664	197	124	454	696	460	52	550	47	683	809	593	328	972	8
9	342	613	29	449	785	623	159	849	760	745	988	743	433	834	37	9
10	841	897	689	778	323	644	21	375	216	17	181	621	7	404	838	10
11	423	118	346	464	231	142	243	950	529	132	417	267	665	725	27	11
12	532	362	933	971	736	182	413	523	978	635	789	771	274	384	899	12
13	618	278	49	499	378	87	270	496	546	832	337	359	445	527	425	13
14	573	715	692	599	888	594	978	97	751	975	377	79	845	6	188	14
15	638	494	48	738	787	140	691	718	113	968	319	797	269	615	82	15
16	169	128	489	727	806	48	662	666	429	862	949	407	988	378	827	16
17	859	418	402	682	475	115	617	74	885	678	636	111	856	535	152	17
18	338	287	955	476	399	842	268	964	307	861	264	652	821	612	877	18
19	175	283	265	598	938	200	18	105	435	241	969	349	669	131	480	19
20	948	186	663	918	189	374	874	297	815	924	2	624	392	254	919	20
21	415	919	156	121	164	711	136	249	740	695	598	895	290	277	721	21
22	798	325	128	358	1	597	833	246	914	8	474	887	582	211	558	22
23	217	828	796	657	862	424	681	334	838	487	864	379	757	183	133	23
24	361	531	882	587	279	318	851	836	202	844	477	382	996	981	982	24
25	177	144	461	288	698	84	857	997	123	187	185	588	961	658	578	25
26	576	198	336	831	154	876	732	388	259	932	354	187	829	432	987	26
27	511	942	184	332	497	188	717	419	198	639	934	303	651	543	64	27
28	411	860	356	739	853	984	258	229	463	814	501	661	291	912	253	28
29	521	764	275	993	514	991	627	38	23	19	854	728	653	340	909	29
30	534	298	173	983	911	564	592	753	561	548	126	676	182	928	544	30
31	810	733	311	768	506	205	417	922	679	80	796	306	595	788	850	31
32	98	428	398	723	330	119	344	724	702	50	410	641	329	172	61	32
33	965	825	957	917	125	196	343	326	194	979	210	628	664	863	553	33
34	659	915	754	455	643	837	982	428	983	223	83	240	321	39	439	34
35	528	907	772	32	522	403	773	376	870	536	61	992	296	228	539	35
36	219	931	789	468	947	634	368	967	224	802	491	648	981	245	191	36
37	512	765	114	668	248	952	147	261	166	36	163	647	631	734	585	37
38	569	618	57	577	161	885	619	285	674	639	818	578	958	317	731	38
39	214	920	848	324	557	155	76	886	478	141	509	766	887	583	322	39
40	951	963	225	276	45	456	482	238	625	582	165	673	333	678	515	40
41	347	898	485	24	493	271	726	226	685	769	490	790	184	719	882	41
42	684	484	556	183	687	389	884	746	898	189	974	994	255	360	372	42
43	381	896	72	473	686	939	143	462	233	884	786	287	215	869	394	43
44	318	469	58	516	441	584	258	820	314	538	70	748	966	4	153	44
45	999	588	171	284	3	968	865	565	422	228	157	85	937	56	369	45
46	51	199	575	284	793	222	129	281	448	777	436	768	46	526	998	46
47	397	586	811	989	263	227	66	367	638	559	479	495	73	353	438	47
48	192	632	288	775	846	799	365	988	813	247	296	488	935	198	385	48
49	427	163	339	414	791	923	767	93	28	758	466	446	871	242	843	49
50	481	737	112	839	852	736	744	916	174	533	31	537	669	763	547	50
51	286	329	262	563	655	716	823	883	977	540	783	213	795	14	63	51
52	160	822	138	921	44	86	89	891	289	880	519	457	168	266	826	52
53	176	781	567	779	458	626	878	945	759	391	237	273	282	995	91	53
54	256	458	894	236	712	823	568	426	819	146	755	71	33	809	26	54
55	713	412	305	312	747	566	552	646	67	92	409	677	611	335	148	55
56	752	774	448	555	528	13	257	43	939	38	42	925	929	697	714	56
57	632	81	574	384	158	139	616	313	188	176	562	77	244	584	239	57
58	571	471	671	926	348	393	364	985	872	585	699	292	792	848	179	58
59	299	232	55	980	388	437	41	776	656	549	127	518	628	272	251	59
60	722	606	852	571	629	667	453	756	554	525	94	940	178	648	735	60
61	438	788	396	28	371	398	858	327	583	221	784	687	345	824	927	61
62	541	645	749	386	134	53	341	835	941	986	35	855	847	795	492	62
63	614	579	956	306	747	517	421	875	383	459	784	195	389	22	9	63
64	781	88	69	637	78	431	794	99	888	596	572	728	498	683	622	64
65	875	331	483	581	294	778	913	866	366	235	873	96	691	293	444	65
66	486	742	883	416	986	68	762	524	181	358	381	954	395	283	34	66
67	944	936	122	588	212	295	568	528	118							67
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	

COLUMNS

Each number from 1-999 appears only once in this table.

MPI DIRECTIVE 917.1
Rev. 2
EXHIBIT D

Sampling guide - Monitoring and Surveillance
(Monitoring - collect only tissue requested on MP Form 23-1)

Residue	Tissue Required	Amount for Each Analysis: Collect from 1 red meat animal	Amount for Each Analysis: Collect from each of 6 birds and Pack separately
Chlorinated Hydrocarbons	Fat	1 pound	1/4 pound
Organo-phosphates	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Fat	" "	1/4 pound
Carbamates	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Kidney	" "	both kidneys
	Fat	" "	1/4 pound
Fungicides	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Kidney	" "	both kidneys
	Fat	" "	1/4 pound
Antibiotics	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Kidney	" "	both kidneys
	Injection site	Total	Total
Sulfa	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Kidney	" "	both kidneys
	Injection site	Total	Total
Ipronidazole	Muscle		1/4 pound-Monitoring** 1 pound-Surveillance
Carbadox	Liver	1 pound	
	Muscle	" "	
DES	Liver	Whole liver ***	

Residue	Tissue Required	Amount for each Analysis** Collect from 1 red meat animal	Collect from each of 6 birds and pack separately
Trace elements: (Arsenic, mercury, copper, lead, other heavy metals)	Liver	1 pound	Whole liver
	Muscle	" "	1/4 pound**
	Kidney	" "	both kidneys
Robenidine	Fat		1/4 pound
	Muscle		1/4 pound
Decoquinate	Liver		Whole liver
	Muscle		1/4 pound**
	Kidney		both kidneys
Other Compounds	Monitoring - Refer to MP Form 23-1 Surveillance - Consult with region through routine channels		

* Less tissue per sample is only acceptable when limited by size of the animal or bird. If serious discrepancies result seek assistance through routine channels. *

** Guideline: 1. Chickens, ducks, fryer roaster turkeys: Use whole thigh less skin and bone.

2. Young and mature turkeys, geese: Use 1/2 thigh less skin and bone.

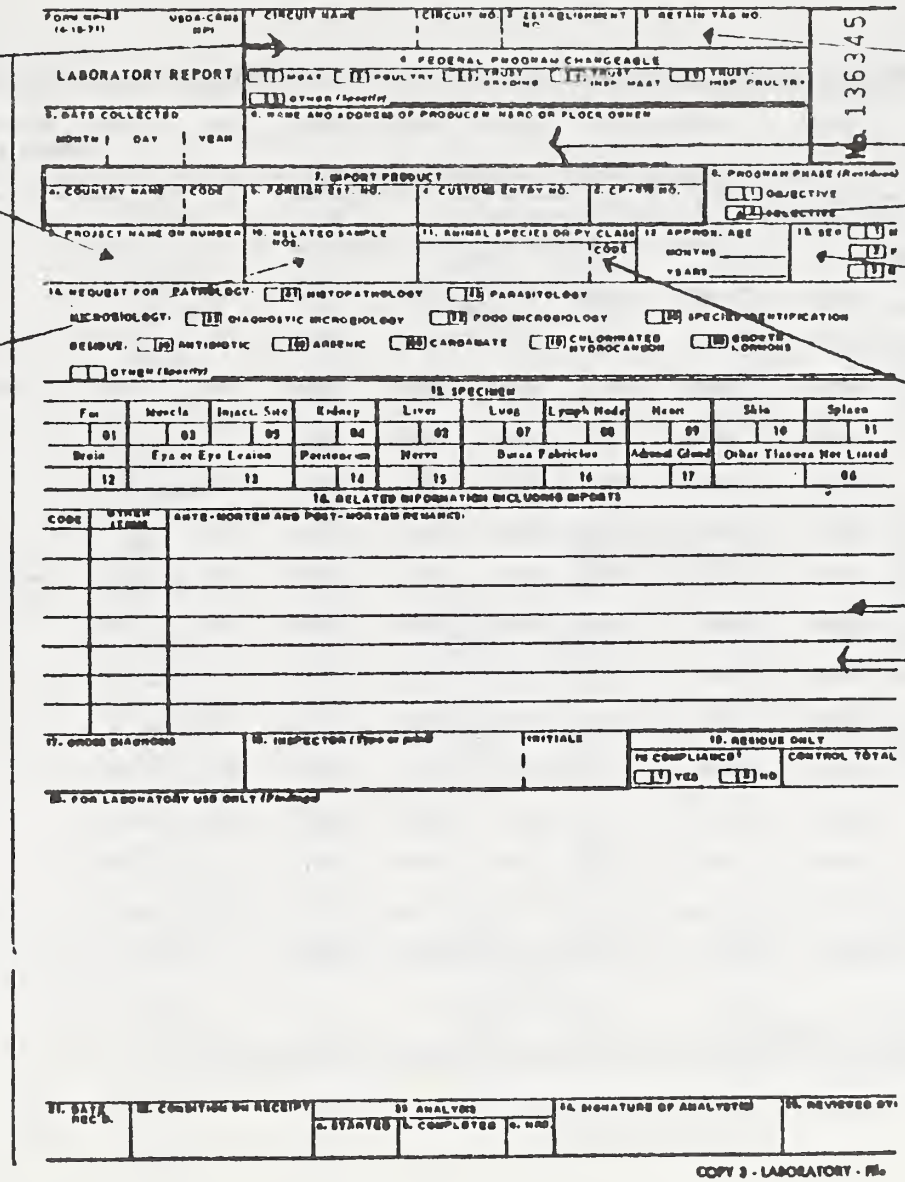
*** For cattle send approximately 4 pounds of liver for monitoring programs, * 2 pounds when surveillance sampling, to laboratory. Retain remainder frozen, * identified and under MPI security for laboratory use if requested. For * sheep, send whole liver initially. Whenever a carcass is retained for DES analysis, collect one pound of muscle in addition to liver.

Attention: IC and Regional Directors--Reproduce and distribute according to indicated codes.

State Code must be recorded.

"Case number" as listed on notification to collect samples.

List numbers of all other animals that are sampled concurrently with animal identified in Box No. 3. If additional space is needed, indicate "see 16" and list in related information section.



Tag number of particular animal being sampled.

Full name and address (including zip code) of owner or producer.

Always mark selective.

Indicate exact sex designation; i.e., bull checked "M" and steer checked "M."

Include species code.

Indicate the name and address of the recognized laboratory if "split sample" is prepared for analysis.

Record back tag number, ear tag number, plant lot number, or any other identification, even if owners name is available.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Chlorinated Hydrocarbon	Tissue	Code	SPECIES: Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
				Action Level - Parts per million** - in rendered fat								
101	Aldrin	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
102	Benzene Hexachloride	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
103	Chlordane	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
104	Dieldrin	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
105	DDT and Metabolites	Fat	01	0500	0500	0500	0500	0500	0500	0500	0500	0500
106	Endrin	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
107	Heptachlor and Metabolites	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030
108	Lindane	Fat	01	0700	0700	0700	0400	0700	0400	0400	0400	0400
109	Methoxychlor	Fat	01	0300	0300	0300	0300	0300	0300	0300	0300	0300
110	Toxaphene	Fat	01	0700	0700	0700	0700	0700	0700	0700	0700	0700
111	Polychlorinated Biphenyls	Fat	01	0500	0500	0500	0500	0500	0500	0500	0500	0500
112	Hexachlorobenzene	Fat	01	0050	0050	0050	0050	0050	0050	0050	0050	0050
113	Mirex	Fat	01	0010	0010	0010	0010	0010	0010	0010	0010	0010
114	Strobane	Fat	01	No action level has been established								
130	Unidentified - Relative Retention Time			Residue Codes 130 through 149 are for information only and are to be disregarded by inspection personnel								
140	Unidentified - Relative Amount											
190	***Polybrominated Biphenyls	Fat	01	0030	0030	0030	0030	0030	0030	0030	0030	0030

** Parts per million The decimal point is understood to be between the second and third position. Example - 0.30ppm is written 0030ppm

*** Limited to State of Michigan.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Antibiotics	Tissue	Code	SPECIES: Cattle	Sheep and Calves	Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
				Action Level - Parts Per Million in Specific Tissue								
201	Penicillin	Muscle	03	*0005	*0005		*0000		*0000	*0001	0001	
		Liver	02	0005	0005		0000		0000	0001	0001	
		Kidney	04	0005	0005		0000		0000	0001	0001	
202	Streptomycin	Muscle	03				*0000		*0000	*0000	0000	
		Liver	02				0000		0000	0000	0000	
		Kidney	04				0000		0000	0000	0000	
203	Chloramphenicol	Muscle	03									
		Liver	02									
		Kidney	04									
204	Tetracycline	Muscle	03		*0025	*0025	*0025		*0025	*0025	*0025	
		Liver	02		0025	0025	0025		0025	0025	0025	
		Kidney	04		0025	0025	0025		0025	0025	0025	
205	Tylosin	Muscle	03	*0020	*0020		*0020		*0020	*0020	*0020	
		Liver	02	0020	0020		0020		0020	0020	0020	
		Kidney	04	0020	0020		0020		0020	0020	0020	
206	Erythromycin	Muscle	03	*0000	*0000		*0010		*0013	*0013	*0013	
		Liver	02	0000	0000		0010		0013	0013	0013	
		Kidney	04	0000	0000		0010		0013	0013	0013	
207	Neomycin	Muscle	03		*0025							
		Liver	02		0025							
		Kidney	04		0025							
208	Oxytetracycline	Muscle	03	*0010	*0010		*0010		*0100	*0100		
		Liver	02	0010	0010		0010		0100	0100		
		Kidney	04	0010	0010		0010		0300	0300		
209	Chlortetracycline	Muscle	03	*0010	*0100		*0100		*0100	*0100	*0100	
		Liver	02	0010	0400		0200		0100	0100	0100	
		Kidney	04	0010	0400		0400		0400	0400	0400	
210	Unidentified Microbiel Inhibitor (UMI)	Muscle	03	NOTE: Unidentified microbial inhibitors require action by inspection personnel.								
		Liver	02									
		Kidney	04									

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Antibiotics (cont'd)	Tissue	Code	SPECIES: Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
				Action Level - Parts Per Million in Specific Tissue								
211	Gentamicin Sulfate	Muscle	03							*0010		
		Liver	02							0010		
		Kidney	04							0010		
212	Lincomycin	Muscle	03				*0010		*0010			
		Liver	02				0010		0010			
		Kidney	04				0010		0010			

* Formal tolerances have been established by Food and Drug Administration.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Organo-Phosphorus Compounds - Tissue		Code	Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
				SPECIES								
				Code - Action Level - Parts Per Million								
301	Coumaphos	Edible	Tissue*	0100	0100	0100	0100	0100	0100	0100	0100	
		Fat	01	0100	0100	0100	0100	0100	0100	0100	0100	
302	Dichlorovos	Edible	Tissue	0002	0002	0002	0010	0002	0005	0005	0005	
		Fat	01	0002	0002	0002	0010	0002	0005	0005	0005	
303	Diazinon	Edible	Tissue	0075	0075	0075						
		Fat	01	0075	0075	0075						
304	Ethion	Edible	Tissue	0075	0075	0020	0020	0020	0020	0020	0020	
		Fat	01	0250	0250	0020	0020	0020	0020	0020	0020	
305	Malathion	Edible	Tissue	0400	0400	0400	0400	0400	0400	0400	0400	
		Fat	01	0400	0400	0400	0400	0400	0400	0400	0400	
306	Parathion	Edible	Tissue									
		Fat	01									
307	Ronnel	Edible	Tissue	0400	0400	0400	0200		0001	0001	0001	
		Fat	01	1000	1000	1000	0300		0001	0001	0001	
308	Ruelene	Edible	Tissue	0100	0100	0100						
		Fat	01	0100	0100	0100						
309	Trichlorfon	Edible	Tissue	0010	0010	0010		0010				
		Fat	01	0010	0010	0010		0010				
310	Methyl Parathion	Edible	Tissue									
		Fat	01									
311	Diazathion	Fat	01	0100	0100	0100	0100	0100				
312	Disulfoton	Edible	Tissue									
		Fat	01									
313	Fenthion	Edible	Tissue	0010	0010				0010	0010	0010	
		Fat	01	0010	0010				0010	0010	0010	
314	Gardona	Fat	01	0150	0150	0050	0150	0050	0025	0025	0025	

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Organo-Phosphorus Compounds	SPECIES								
	Tissue Code	Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
330	Unidentified - Relative Retention Time	Residue Code 330 through 349 are for information only, and are to be disregarded by inspection personnel.								
340	Unidentified - Relative Amount									
*	Edible tissue used in lieu of muscle, liver, and kidney.									

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

				SPECIES								
				Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
Residue Code	Trace Metals	Tissue	Code	Action Level Parts Per Million								
401	Arsenic	Muscle	03	0070			0050		0050	0050		
		Liver	02	0270			0206		0200	0200		
402	Mercury*											
403	Copper*											
404	Lead*											
405	Zinc*											
406	Cadmium*											
407	Antimony*											
408	Selenium*											
409	Aluminum*											
410	Titanium*											
411	Iron*											

* Tolerances for these trace metal in meat food animals have not been established by a Federal authority. -- APHIS is gathering information concerning normal background levels.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Hormone	Tissue Code	Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
			Action Level Parts Per Billion								
501	Diethylstilbestrol*	Liver 02	0000		0000						
		Muscle 03	0000		0000						
502											
503											
504											
505											
506											
507											
508											
509											
510	Zearalenol (Zeranol)*	Edible	2000		2000						
511											
512											
513	Zearalenone**										

* The Federal tolerance for this compound is zero, the APHIS action level is based on the limit of detection of the method.

** A natural occuring substance - no action level established.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Sulfonamide Drugs	Tissue	Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
			Action Level * Parts Per Million in Tissue								
801	Sulfaethoxypyridazine	Edible	0010	0010		0010			0010		
802	Sulfachlorpyridazine	Edible	0010	0010		0010					
803	Sulfadimethoxine	Edible	0010	0010				0010	0010		
804	Sulfanitran	Edible						0000			
805	Sulfamethazine	Edible	0010	0010		0010					
806	Sulfachloropyrazine	Edible									
808	Sulfamerazine	Edible									
809	Sulfathiazole	Edible				0010					
810	Sulfaquinoxaline	Edible									
811	Sulfabromomethazine	Edible									
812	Sulfamethizole	Edible									
813	Sulfanilimide	Edible									
814	Sulfomyxin	Edible						0000	0000		
830	Unidentified Relative Retention	Residue codes 830 through 840 are for information only, and are to be disregarded by inspection personnel.									
840	Unidentified Relative Amount										

* Terminal residues greater than 0010 are not permitted for any sulfonamide drug.

ACTION LEVEL IS MAXIMUM ALLOWED BY USDA/APHIS/MEAT AND POULTRY INSPECTIONS

Residue Code	Drugs - General	Tissue	Code	Cattle	Calves	Sheep and Goats	Swine	Horses	Chickens	Turkeys	Ducks and Geese	Rabbits
				Action Level in Animal Tissue								
901	Clopidol	Liver	02	*0150	0150	0150	0020		1500	1500		
		Muscle	03	0020	0020	0020	0020		0500	0500		
		Kidney	04	0300	0300	0300	0020		1500	1500		
902	Furazolidone	Edible Tissue		**			0000					
903	Nitrofurazone			**			0000					
904	Decoquinate	Liver	02	*					0200			
		Muscle	03						0100			
		Kidney	04						0200			
905	Monensin	Edible Tissue		*0005					0005			
906	Ipronidazole	Edible Tissue		**						0200		
907	Carbadox	Edible Tissue		**			0000					
908	Robenidine Hydrochloride	Fat	01	*					0020			
		Edible Tissue							0010			

* Parts per million

** Parts per billion

MPI DIRECTIVE 917.1
Rev. 2
EXHIBIT G

RESIDUE IDENTIFICATION

100 Chlorinated pesticides
101 Aldrin
102 Benzene hexachloride
103 Chlordane
104 Dieldrin
105 DDT and Metabolites
106 Endrin
107 Heptachlor and Metabolites
108 Lindane
109 Methoxychlor
110 Toxaphene
111 PCB's
112 Hexachlorobenzene
113 Mirex
114 Strobane
130 Unidentified rel. ret.
140 Unidentified rel. amt.
191 PBB

200 Antibiotics
201 Penicillin
202 Streptomycin
203 Chloramphenicol
204 Tetracycline
205 Tylosin
206 Erythromycin
207 Neomycin
208 Oxytetracycline
209 Chlortetracycline
210 Unidentified microbial inhibitor
211 Gentamicin sulfate
212 Lincomycin

300 Organic phosphorus pesticides
301 Coumaphos
302 Dichlorvos vapona
303 Diazinon
304 Ethion
305 Malathion
306 Parathion
307 Ronnel
308 Ruelene
309 Trichlorfon
310 Methyl parathion
311 Dioxathion
312 Disulfoton
313 Fenetrothion
314 Gardona
330 Unidentified rel. ret.
340 Unidentified rel. amt.

400 Trace elements
401 Arsenic
402 Mercury
403 Copper
404 Lead
405 Zinc
406 Cadmium
407 Antimony
408 Selenium
409 Aluminum
410 Titanium
411 Iron

500 Hormones
501 Diethylstilbestrol
502 Dienestrol diacetate
503 Estradiol benzoate
504 Melengestrol acetate
505 Progestrone
506 Testosterone
507 Testosterone propionate
508 Medroxyprogesterone acetate
509 Chlormadinone acetate
510 Zearalanol, (zeranol)
511 Estradiol monopalmitate
512 Hexestrol
513 Zearalenone

600 Carbamates
601 Carbaryl

700 Herbicides
701 2,4-D
702 2,4,5-T

800 Sulfa
801 Sulfaethoxypyridazine
802 Sulfachlorpyridazine
803 Sulfadimethoxine
804 Sulfanitran
805 Sulfamethazine
806 Sulfachloropyrazine
807 Sulfamethoxypyridazine
808 Sulfamerazine
809 Sulfathiazole
810 Sulfaquinoxaline
811 Sulfabromomethazine
812 Sulfamethiazole
830 Unidentified rel. ret.
840 Unidentified rel. amt.

900 Drugs, general
901 Clopidol
902 Furazolidone
903 Nitrofurazone
904 Decoquinate
905 Monensin
906 Ipro idazole
907 Carb dox
908 Robenidine

SPECIES CODE

01 Horse
11 Bulls
12 Steers
13 Cow
14 Heifer
20 Calves
30 Sheep
40 Goats
50 Swine
61 Young chickens
63 Mature chickens
71 Fryer Roaster
72 Young turkeys
73 Mature turkeys
81 Ducks
82 Geese
91 Rabbits

TISSUE IDENTIFICATION

01 Fat
02 Liver
03 Muscle
04 Kidney
05 Injection lesion
06 Other
07 Lung
08 Lymph node
09 Heart
10 Skin
11 Spleen
12 Brain
13 Eye or Eye Lesion
14 Peritoneum
15 Nerve
16 Bursa fabricus
17 Adrenal gland

ATTACHMENT #2

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
Meat and Poultry Inspection Program
Washington, DC 20250

MPI BULLETIN 77-114
8/26/77

ACTION BY: Inspectors in Charge at Slaughter Plants

INFORMATION FOR: Regional Directors, Area and Circuit Supervisory Personnel and MPI Laboratories

Residue Sampling Requirements

This bulletin cancels MPI Bulletin 76-51, and supplements MPI Directive 917.1, Rev.2, dated 1/22/76.

1. Instructions for preparation and distribution of MP Form 23-1 are supplemented by the following:

   a. Record the name of the integrated operation along with the name, address, and zip code of the producer when management is integrated.

   b. Print "Fancy" in the species block to distinguish fancy veal calves that are confined and are fed milk replacer from calves managed by more conventional methods. Record in the same block the approximate age of the calf.

   c. Record the retain tag number of the standby DES liver sample in the "other identification" block.

   d. The collection date must be corrected when samples are not collected on the preprinted collection date. Inaccurate slaughter dates complicate followup actions with producers.

   e. After removal of tear strip, protect the MP Form 23-1 packet in an unsealed plastic bag, and tape on top of insulated lid with a strand of tape prior to closure of outer carton.

DISTRIBUTION: A-O by IC P,Q,S,U-2 by RO	CATEGORY: K-Laboratory	REGS: MANUAL: Subpart 11-E	OPI: REP

2. The following information supplements MPI Directive 917.1 Rev. 2, Exhibit D, Sampling Guide-Monitoring and Surveillance; prescribed procedures will be followed unless special directions are provided by the regional director:

a. Each tissue from each livestock animal or bird must be bagged separately. When required, compositing will be done by the laboratory.

b. Analyses in livestock are performed on single tissues submitted from one animal.

c. Analyses in poultry are performed on a composite (prepared by laboratory) of like tissues from six birds from the same flock.

d. The Veterinary Medical Officer (VMO) will receive instructions for followup sampling of established residue cases from the region through accepted channels.

e. Request assistance through accepted channels for any residue problem suspected during ante-mortem or post-mortem inspection.

3. Recognized laboratories are private or other Non-Program laboratories whose results are acceptable to MPI. Such laboratories are only recognized for analysis of the compounds for which they have proven their analytical capability to MPI. A current listing of recognized laboratories for each group of compounds is provided to regional offices. These laboratories are used by producers or packers at their expense when required by surveillance programs, or to expedite analyses for their convenience. The results are not official until cleared through accepted MPI channels.

4. Preparation of split samples for recognized and MPI laboratory. The following criteria must be met before a recognized laboratory test result is acceptable.

a. A single tissue type from one livestock animal or one bird is chopped, mixed, and divided into two equal portions--one for each laboratory. The same procedure is used to collect all required samples. Compositing when required will be done by the laboratory. Every effort must be made to provide the required amount of tissue for each laboratory. The amount of poultry liver and kidney for each laboratory will be one-half the available tissue.

b. Record in block 16 of MP Form 23 "split sample" followed by the name of the recognized laboratory.

c. Prepare a separate identically completed MP Form 23 for transmittal with the sample to the recognized laboratory. Mark out the preprinted serial number and record immediately below it the serial

number of the MP Form 23 prepared for the MPI portion of the sample. The sample is unofficial without this identification and resampling may be required.

d. MPI shipping containers must not be supplied to industry for shipping split samples to recognized laboratories. It is industry's responsibility to provide adequate containers and transportation. Sample preparation must be under MPI supervision.

5. Supplemental instructions for completion of MP Form 23:

a. Complete a separate form for each livestock animal tested.

b. Complete a separate form for each lot of birds sampled.

c. Record in block 9 the region's case number for established cases. (Example: 3-456-77)

d. In block 16 record sample plan information needed by laboratory including, when applicable, "prepare six bird composite," "individual analyses," and "split sample" (followed by name of recognized laboratory).

e. Record in block 16 relationships to other samples currently under evaluation on other laboratory forms for the same case. Common example are: "Number 1 of 5 required samples," "Number 2 of 5 required samples," "Number 1 of 5 additional producers from integrated operation," "Number 2 of 5 additional producers from integrated operation."

f. Record in block 10 the retain tag numbers, MP Form 23 numbers, or the number of other forms currently under consideration on the same case. Continue in block 16 if necessary.

g. Remove copy of MP Form 23 for inspector's records. The sample copy number 4 may be wrapped around the sample bag. Protect the remaining packet, with carbons intact, in a plastic bag and attach to top of insulated lid with a strand of tape prior to closure of outer carton.

6. Instructions for sample preparation in monitoring and surveillance phases:

a. Each sample bag must be <u>tightly closed</u> to prevent leakage if thawing occurs.

b. Identify tissue type on each bag. (Example: liver)

c. Additional identification for surveillance samples: Each bag must be identified with a specific livestock animal or bird by a retain tag or other numerical designation. Example: Most poultry sample plans require random sampling of 30 birds for laboratory compositing of like tissues into five groups of six. Identify and mark the birds 1 through 30. Identify tissue samples with the same number as the source bird. If split samples are prepared for a recognized laboratory, the same identification must be used for both split samples from the same bird.

7. Preparation of shipping container for transmittal to MPI Laboratory and return:

a. An approved insulated shipping container with the correct number of solidly frozen coolant canisters must be used. Coolant canisters must not be removed to increase sample capacity of container. If adequate shipping containers are not available the inspector should notify his supervisor.

b. Samples must be thoroughly frozen (approximately 0°F or below) prior to mailing. Twenty-four hours should be adequate freezing time after collection. The bagged samples are to be frozen before placing in the shipping container. Allow for expansion during freezing. Do not force tissues into shipping containers.

c. Fill partially filled shipping containers with crumpled newspaper or other clean waste paper to reduce possibility of damage in transit.

d. Samples must be sent on the next working day to the designated laboratory. It is permissable to send any day of the week; however, the inspector is responsible for contacting local postal authorities to determine mailing times that will minimize holdovers and delays in transit. Based upon this information, mailing schedules can be modified accordingly.

e. The airmail side of the mailing frank--MP Form 13, must be used for transmittal of all samples to the MPI laboratory. Airmail stickers or notations used along with regular mail franks will not be honored by the post office for first class (airmail) delivery.

f. The inspector must provide a return addressed regular mail frank for return of the container by the laboratory. Utilize the regular mail side of the same MP Form 13 used to airmail the sample (when using containers with a frank card window). On boxes with a double flap lid (no window), attach a return address regular mail frank to flap not used for the laboratory addressed frank.

g. Close inner containers with rubber bands or straps as required to insure adequate closure. Unnecessary use of tape on insulated containers and excessive use of tape on outside cartons causes excessive damage to cartons when removed and increases opening time in the laboratory. The use of metal bands for container closure is unacceptable since it may damage containers.

8. DES sampling procedures:

a. Monitoring phase DES samples must be collected at random from animals appearing normal on ante- and post-mortem inspection and having normal appearing livers.

b. Surveillance phase DES samples are to be collected from animals regardless of health status when the VMO suspects a DES residue problem. Such animals must be retained. If a lot of more than five animals is suspected, contact the region through accepted channels for a sample plan and followup actions.

c. Through improvement in analytical capability the MPI laboratory can confirm DES in liver tissue by mass spectroscopy with the originally submitted portion of the monitoring sample. An increase in sample size is required to meet commitments to provide FDA with tissue for testing and meeting legal requirements leading to prosecution.

d. Submit approximately 4 pounds of liver for cattle DES monitoring samples. Use as a guide the amount of frozen liver that will completely fill the sample space in the shipping container. Submit 2 pounds of liver for cattle surveillance samples. Sheep monitoring and surveillance samples consist of the entire liver. Surveillance samples from both species require, in addition, one pound of muscle when retention of carcasses is required.

e. The rate of DES samples arriving thawed and unacceptable at the laboratory is high. Follow prescribed preparation and transmittal procedures (item 7 this Bulletin) to eliminate causes under MPI control.

f. After collecting any cattle DES sample, the entire unsampled portion of the liver must be identified by the same retain tag as the laboratory sample and is referred to as a "standby sample". This standby sample is to be frozen and held under MPI security.

g. Every effort should be made to locate freezer space for standby samples when "U.S. Retained" freezer space is not available in the slaughter plant. If none can be found, please request advice from

your supervisor. It is absolutely essential that standby samples be handled correctly. The sampling inspector is the person responsible for this requirement.

h. When a DES Sample is negative, as indicated by the returned laboratory form or official telephone notification, the standby sample for this liver can be released.

i. If the results are positive, hold the standby liver for 30 days to allow the laboratory to request additional tissue if needed to meet commitments to FDA, plant management, or producer. The VMO may receive a request by telephone through accepted channels to submit the entire standby sample to a specified laboratory when further laboratory study is necessary. At least 4 to 8 pounds of tissue should be available and shipped to the laboratory. Record in block 16 of MP Form 23 "Standby Sample", the original MP Form 23-1 preprinted number, collection date of original sample, and number of containers used for shipment of standby sample (Example: "Standby tissue, 94067N, 8/8/75. 2 containers.") If two or more containers are required, prepare only one MP Form 23. Enclose copy 5 of the MP Form 23 in the second container and copy 4 in the third container if needed. The appropriate remaining copies with carbons intact go in the first container. If no request is made in 30 days following report of the confirmed positive, destroy the standby sample.

9. Actions to be taken when cattle DES standby samples are unavailable:

a. If freezer facilities cannot be found for holding a standby sample, record "No Standby Sample" and reason is block 16 of MP Form 23 or in block listing required tissues of MP Form 23-1. The inspector must consult with his or her supervisor for alternative means of holding the samples.

b. If the standby sample, as defined in this bulletin, is not available when requested, the VMO will prepare a letter of explanation to his supervisor. One copy will be transmitted through accepted channels to the regional office.

10. Availability of test results to official plants:

a. For prompt disposition of retained product, surveillance test results are reported to the inspector through accepted channels by telephone.

b. Test results should be reported verbally to management by the inspector.

c. Completed laboratory forms (monitoring and surveillance) shall be made available for review by management of the plant where product was sampled. Such forms may be reproduced by plant management without cost to the Program.

d. Monitoring phase sampling plans are confidential and must not be provided to plant management. Management may be verbally informed of the reason for sampling at the time of sample collection.

NOTE: To be reproduced and distributed by STS-1C and regional offices according to indicated codes.

Donald Houston

Acting Associate Deputy Administrator
Meat and Poultry Inspection Program

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
MEAT AND POULTRY INSPECTION PROGRAM

RESIDUE MONITORING PROGRAM

NAME AND ADDRESS OF OWNER

ATTACHMENT #3

NO. 213833 NO

OTHER IDENTIFICATION

SPECIES	STATE OF ESTABLISHMENT	ESTABLISHMENT NO.	LOT SIZE
MATURE CHICKEN 63	UTAH 149	P 1313	

COLLECT FOLLOWING TISSUE	COLLECT TISSUE ON	SEND TISSUE TO THIS ADDRESS
FAT	7- 6-79	601 USDA-FSQS-SCIENCE-WESTERN LAB P.O. BOX 2423 SAN FRANCISCO, CALIF. 94126
SIGNATURE OF INSPECTOR	DATE SENT TO LABORATORY	

FOR LABORATORY USE ONLY

DATE TISSUE RECEIVED: 7-12-79

DATE TISSUE ANALYZED: 8-3-79

TISSUE TO BE ANALYZED FOR: 100

DATE & TIME COLLECTED: 7-6

INTO FREEZER: "

TISSUE CODE	RESIDUE CODE	AMOUNT	TISSUE CODE	RESIDUE CODE	AMOUNT	TISSUE CODE	RESIDUE CODE	AMOUNT	TISSUE CODE	RESIDUE CODE	AMOUNT
	113	1565									

SIGNATURE OF ANALYST

REVIEWED BY

APHIS FORM 23-1 (3/78)

SPECIES	TISSUE	NO.
MATURE CHICKEN	FAT	213833 NO

LABORATORY ANALYSIS REQUESTED	COLLECT TISSUE	DATE SENT TO LABORATORY	NAME OF INSPECTOR
100	7-6-79	7-16-79	L R S Bryan

APHIS FORM 23-1 (3/78) PREVIOUS EDITIONS MAY BE USED

ESTAB. P 1313 AREA 11E

COPY 3-Inspector

• • • IMPORTANT • • •
FREEZE SAMPLE IMMEDIATELY

RECORD COLLECTION AND FREEZING TIMES ABOVE

U.S. DEPARTMENT OF AGRICULTURE — FOOD SAFETY AND QUALITY SERVICE

Memorandum

ATTACHMENT #4

SUBJECT Turnaround Time for Surveillance and Monitoring Phase Samples

DATE: 21 SEP 1978

TO : Laboratory Directors

We want you to know that Department officials, including Assistant Secretary Carol Tucker Foreman, are very pleased that you have achieved and maintained our turnaround time for surveillance and monitoring phase samples. Science has been asked to continue the good work. The success of achieving the turnaround time has had a great impact on the FSQS efforts to reduce sulfa and other residues.

In the near future, even if the turnaround time data is computerized, we will still have a need to know the reason(s) why the reporting or analysis of certain samples has been delayed.

We would appreciate it, therefore, if you would please state on the copy of MP Forms 23 and 23-1 forwarded to Mr. Ettinger's office, the reason(s) for exceeding the following turnaround times:

3 working days - Surveillance Phase - In Compliance
5 working days - Surveillance Phase - Out of Compliance
14 calendar days - Monitoring Phase - In and Out of Compliance

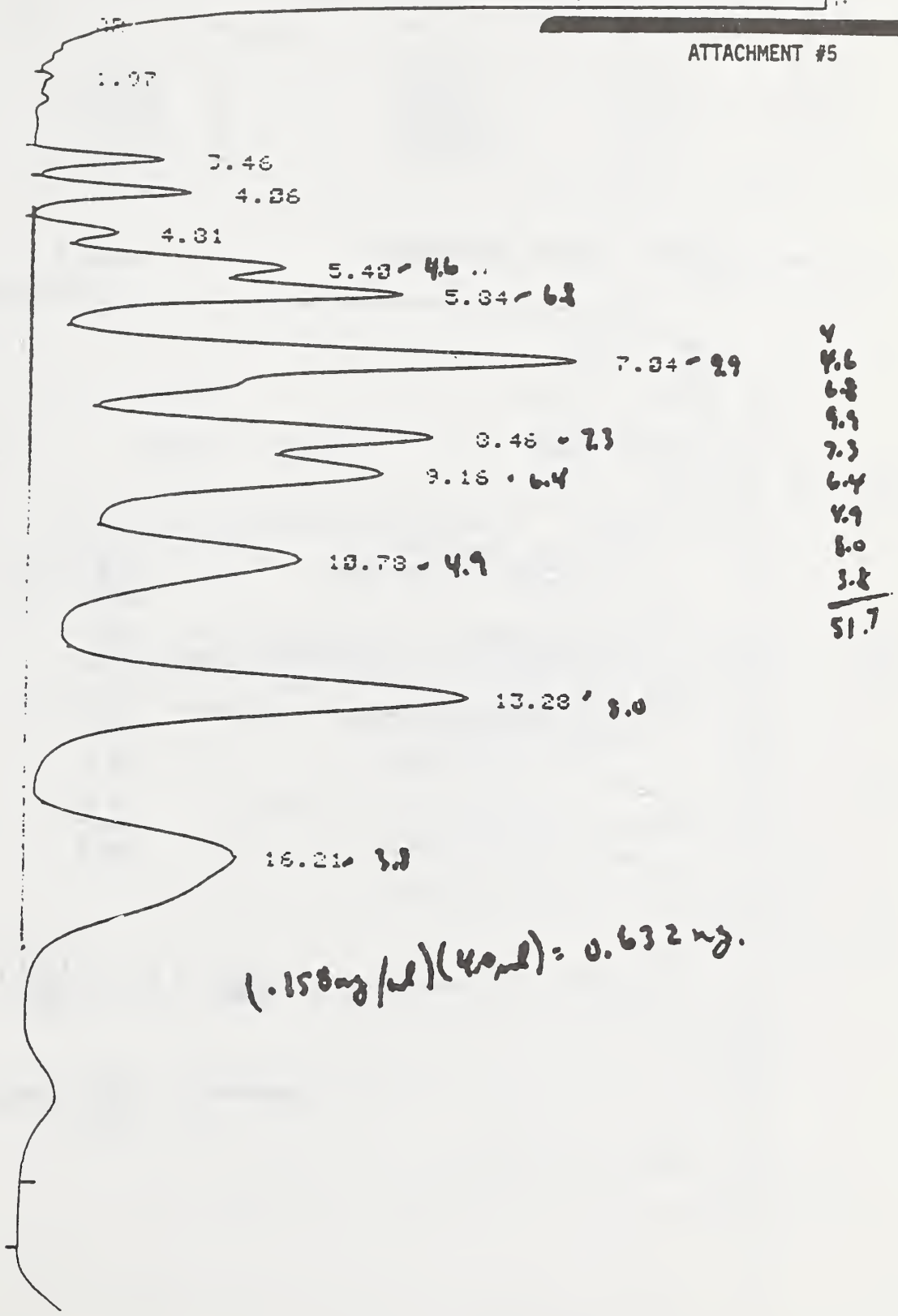
This information will reduce the number of telephone inquiries by the Planning, Review and Evaluation Section when the turnaround times exceed the number of days listed above. A very good review of the reason can be presented because your valuable time will not be disturbed by telephone calls.

Ronald E Engel

Ronald E. Engel
Acting Deputy Administrator
for Science

Aroclor 1260 STD 0.158 mg/mL. 4.0 mL

ATTACHMENT #5



4
4.6
6.8
9.9
7.3
6.4
4.9
8.0
3.8
51.7

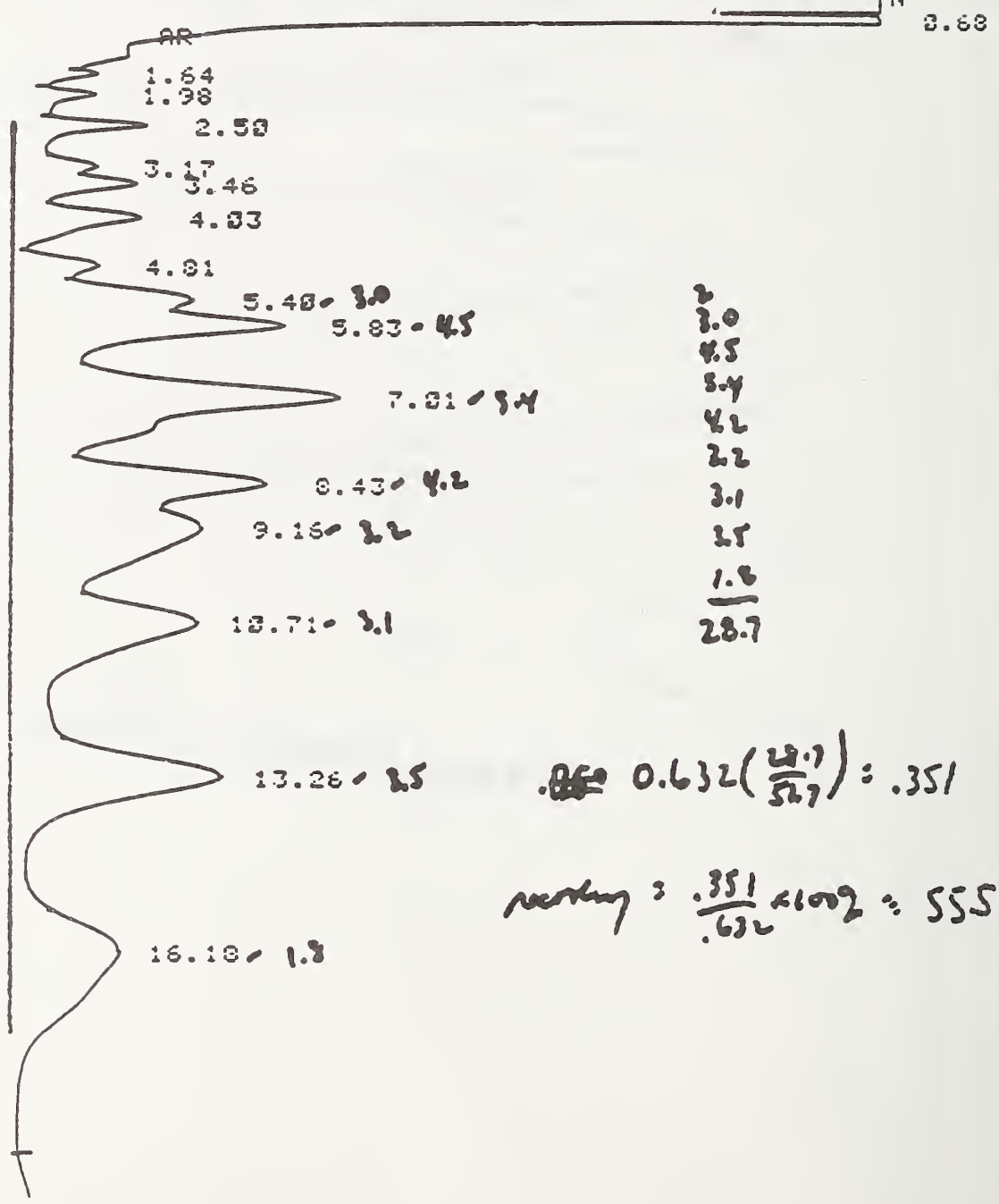
(.158 mg/mL)(40 mL) = 0.632 mg.

RUN # 693 AUG/02/79 TIME 12:18:25

RT	EXP RT	AREA	CAL #	AMT
4.36	4.17	45760	6	0.088
5.40	5.07	71400	7	0.281
7.34	7.22	250800	9	0.963
9.11	9.31	183600	11	0.581
13.35	13.03	283400	12	0.667

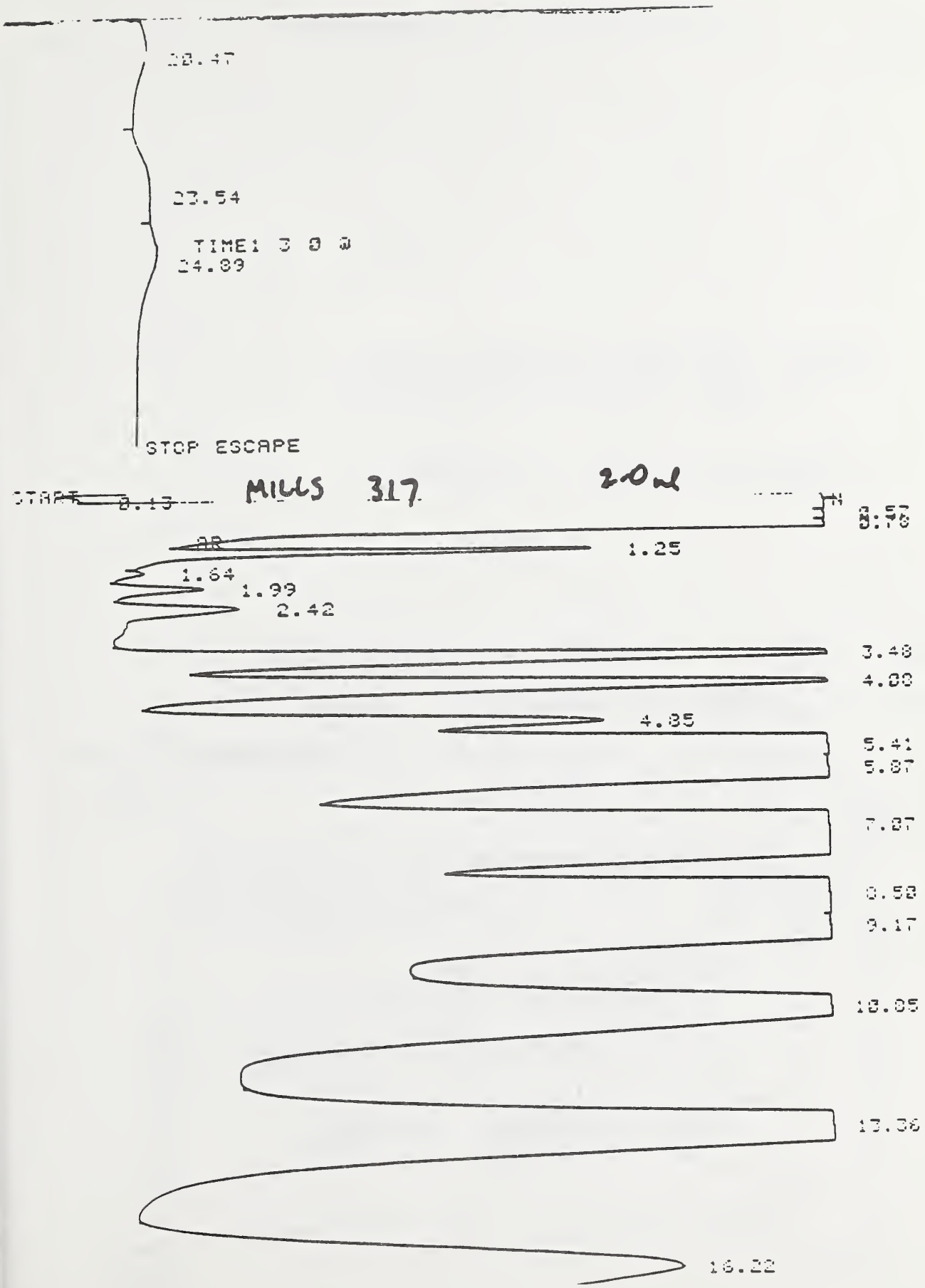
DIL FACTOR: 1.0000 E+ 0

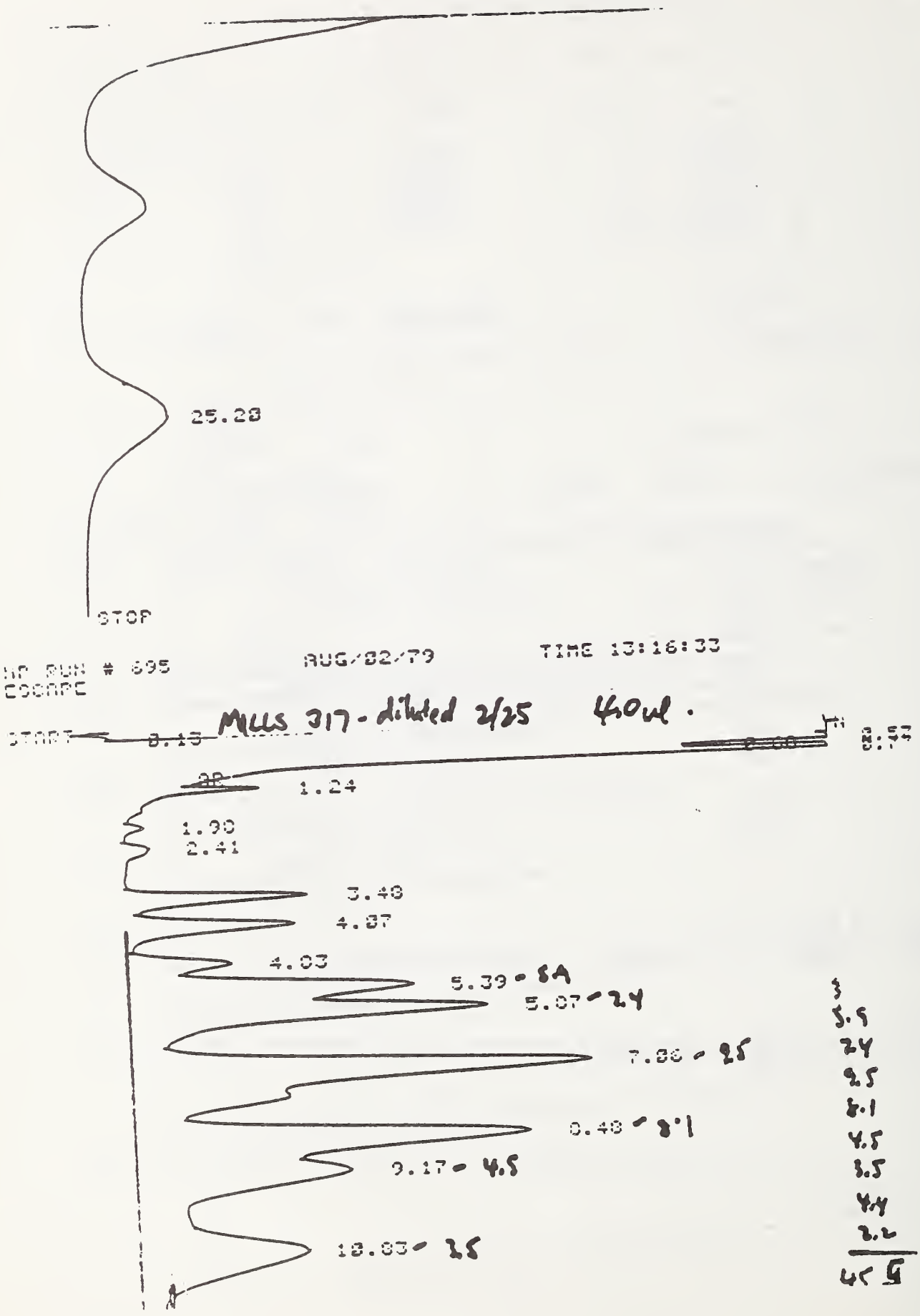
START — Mills 1260 Recovery — F.O.L.

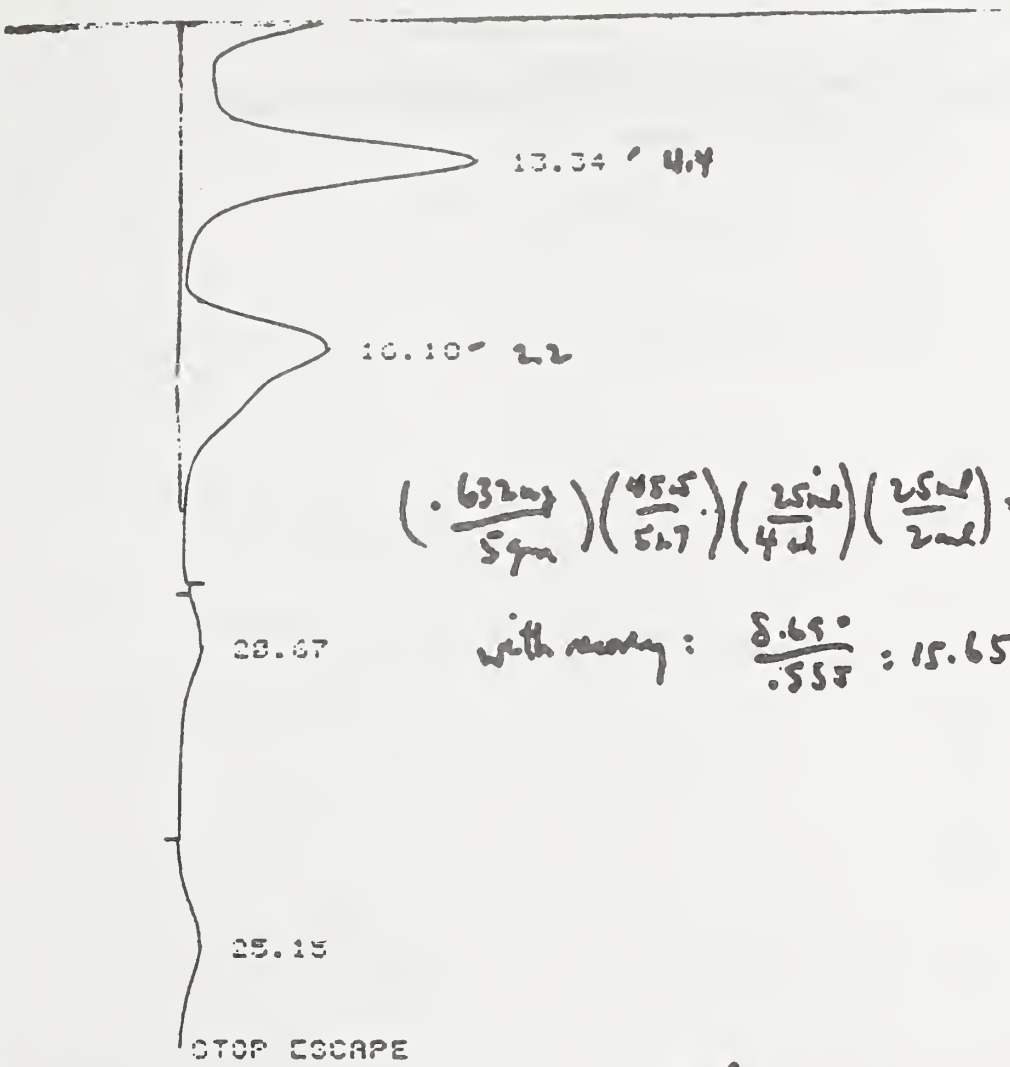


.866 $0.632\left(\frac{28.7}{52.7}\right) = .351$

recovery $= \frac{.351}{.632} \times 100 = 55.5\%$


23.47
23.54
TIME: 3 0 0
24.09
STOP ESCAPE
MILLS 317
20 ml
START 0.13
8:57
8:76
AR
1.25
1.64
1.99
2.42
3.48
4.00
4.85
5.41
5.87
7.87
8.58
9.17
10.05
13.06
16.22

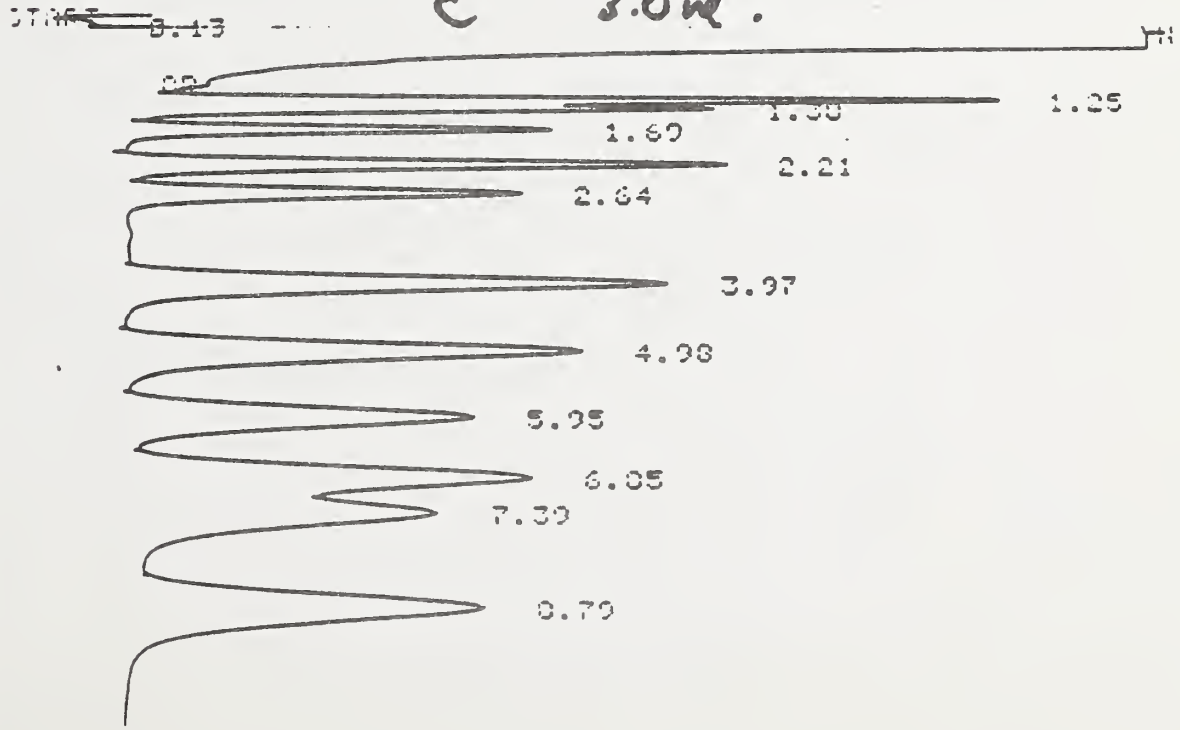

25.28
STOP
HP RUN # 695
COORPE
AUG/02/79
TIME 13:16:33
Mills 317 - diluted 2/25 40ul.
START
8.13
8:57
1.24
1.90
2.41
3.48
4.87
4.03
5.39 - 5.9
5.07 - 2.4
7.80 - 2.5
8.48 - 8.1
9.17 - 4.5
10.83 - 2.5
5.9
2.4
2.5
8.1
4.5
3.5
4.4
2.2
45.5

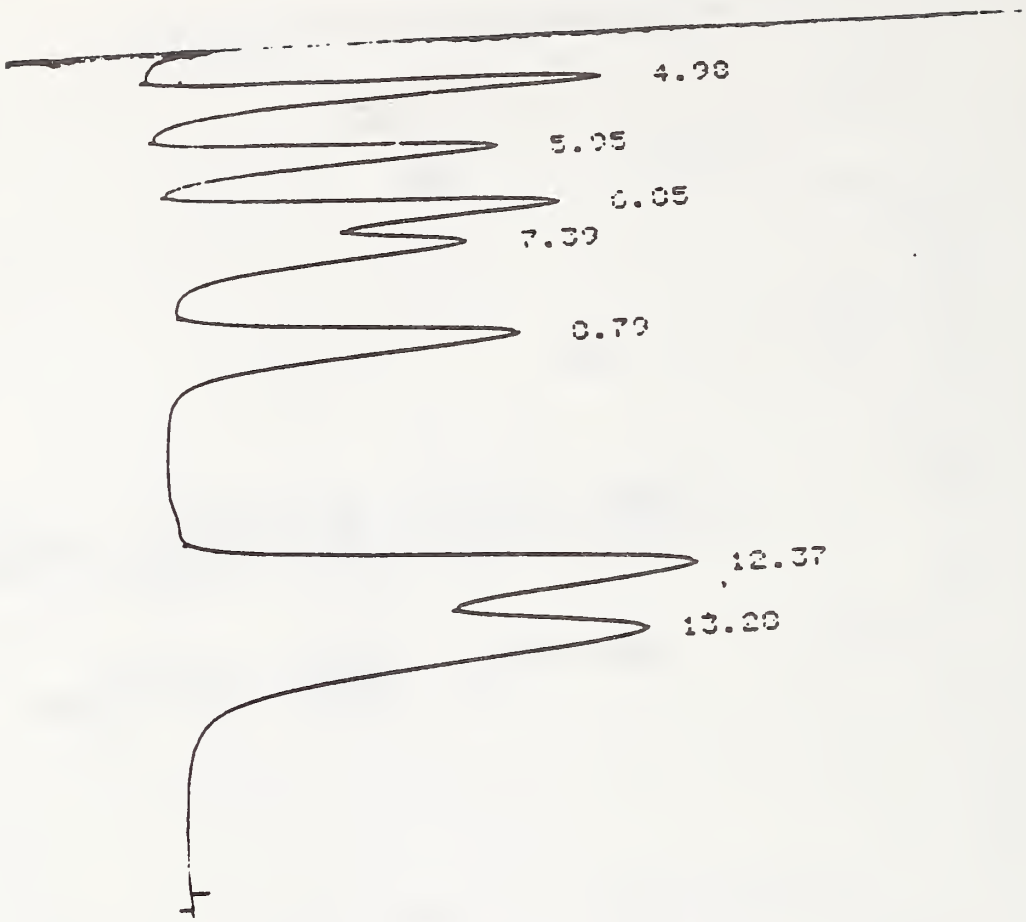


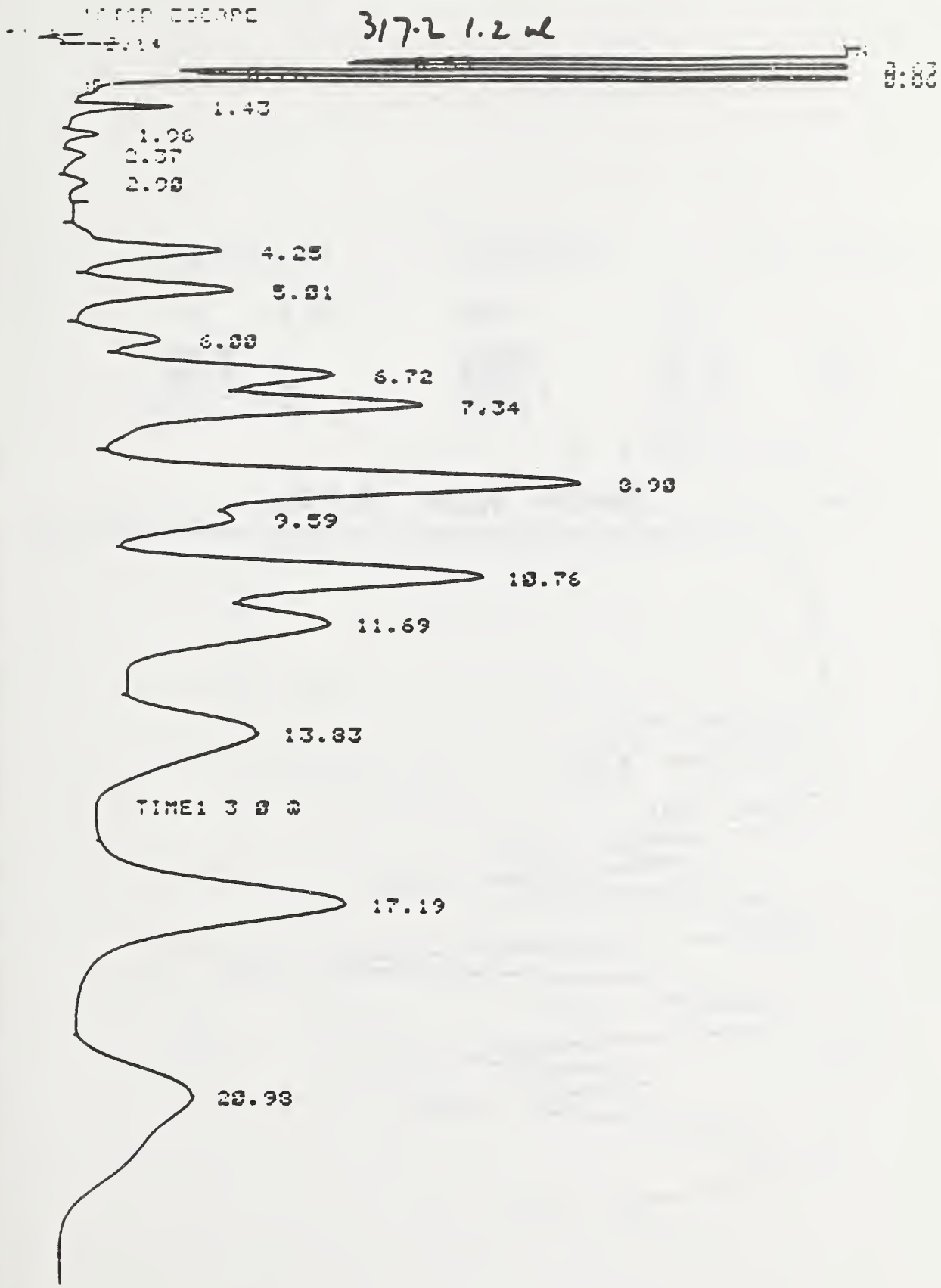
$$\left(\frac{.632\,mg}{5\,gm}\right)\left(\frac{455}{54.7}\right)\left(\frac{25\,ml}{4\,ml}\right)\left(\frac{25\,ml}{2\,ml}\right) = 8.690\,ppm$$

with reading: $\frac{8.69}{.555} = 15.654\,ppm$

c 3.0 ml.



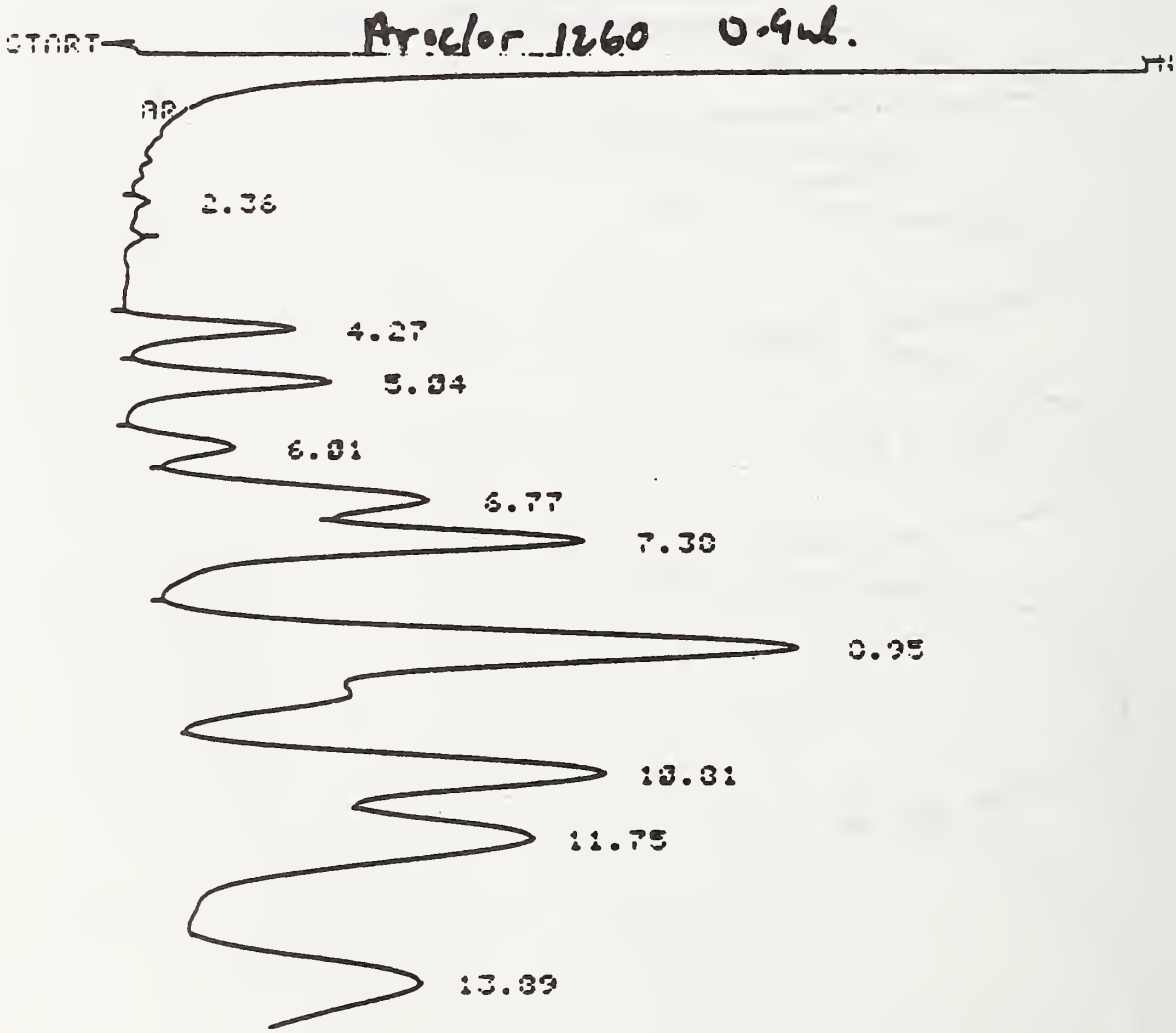

4.98
5.05
6.05
7.39
8.79
12.37
13.20

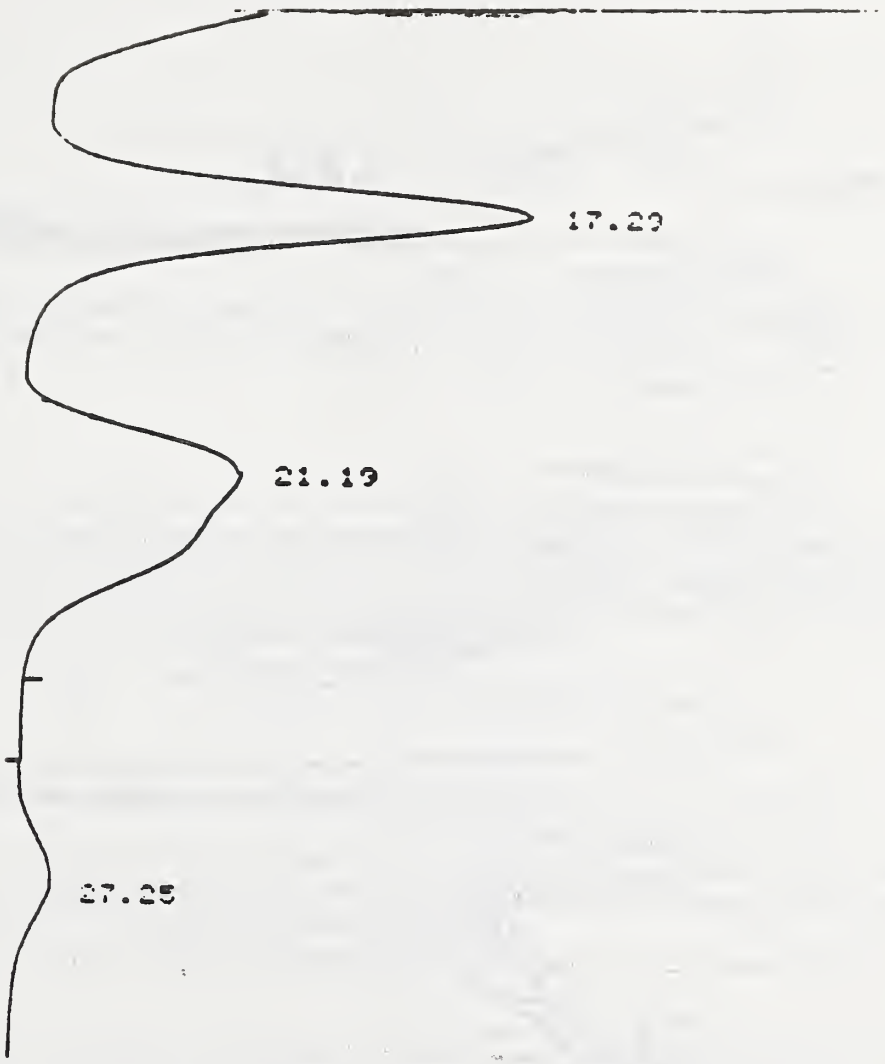

317.2 1.2 ml
0:02
1.43
1.96
2.37
2.98
4.25
5.01
6.00
6.72
7.34
9.00
9.59
10.76
11.69
13.03
TIME: 3 0 0
17.19
20.98

HP RUN # 657 JUL-27-79 TIME 07:41:50
ESTD

RT	EXP RT	AREA	CAL #	AMT
1.43	1.42	13630	3	0.057
4.25	4.17	32220	6	0.062
7.34	7.22	115800	9	0.445
13.03	14.15	167700	13	1.110

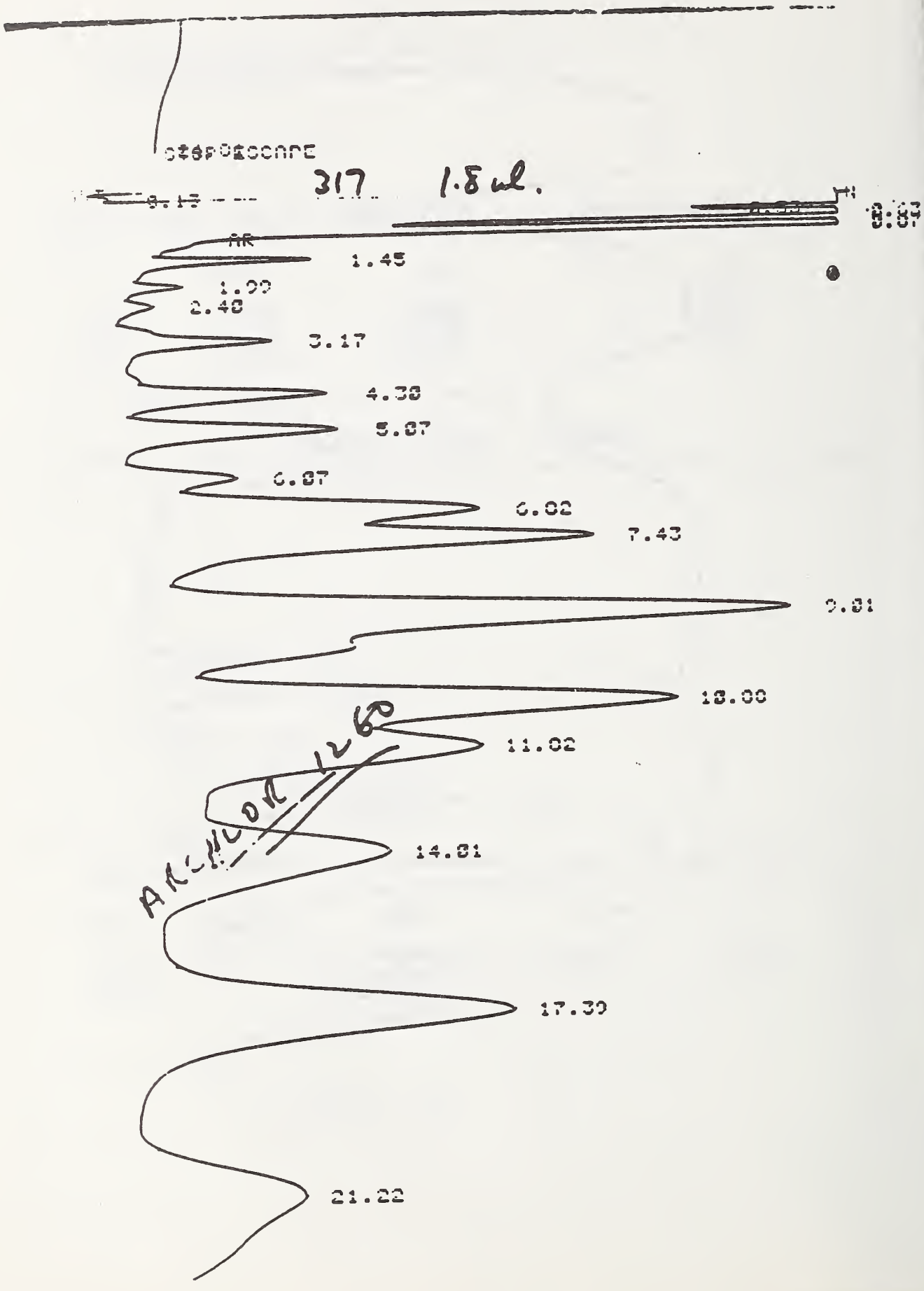
DIL FACTOR: 1.0000 E+ 0





ID RUN # 650 JUL/27/79 TIME 00:14:05
ISTD

RT	EXP RT	AREA	CAL #	AMT
4.27	4.17	21430	0	0.041
7.33	7.23	111080	0	0.458


317 1.8 ml.
1.45
2.48
3.17
4.38
5.87
6.87
8.02
7.43
9.81
10.00
11.02
ACETONE 1:6
14.81
17.39
21.22

PART 5—BIOLOGICAL RESIDUE PROCEDURES

5.001 Chlorinated Hydrocarbon Analysis

Because chlorinated hydrocarbon pesticides are stored in fat, or fatty tissue and tolerances are set for these residues in fat, all such analyses are reported on the basis of the extracted or rendered fat.

5.001A. Theory

The sample is dissolved in petroleum ether and extracted with acetonitrile. The acetonitrile extracts are diluted with water to partition the pesticide residues into petroleum ether. The residues are purified by chromatography on a Florisil column, eluting with mixtures of petroleum and ethyl ethers. Residues in the concentrated eluates are measured quantitatively by gas-liquid chromatography or semi-quantitatively by thin layer chromatography. Identification is by a combination of gas-liquid and thin-layer chromatography.

5.001B. Apparatus

(a) Chromatographic columns: 22mm id x 300 mm with teflon stopcocks and coarse fritted plate.

(b) Alternate Column: Chromatographic columns, 22mm id x 300 or 400 mm without stopcocks. With coarse fritted plate. - (when this column is used, it is topped with anhydrous sodium sulfate powder for flow control).

(c) Filter tubes: Approximately 22mm x 200mm with a short delivery tube and a coarse fritted plate (a glass wool plug can also be used).

(d) Kuderna-Danish Concentrators: Five hundred ml with 5 or 10 ml volumetric receiving flasks or graduated tubes (Kolmer or Mills types: Kontes Glass Company, Vineland, New Jersey 08360, Catalog No. K-570000, K-621400, or equivalent.)

(e) Alternate concentrator: If the solutions can be made to a volume of 25 ml, an Erlenmeyer flask with a 24/40 standard taper joint with a three ball Snyder column may be used.

(f) Separatory funnels: Teflon stopcocks - 500 ml and 125 ml.

(g) Thin layer apparatus and accessories: Desaga/Brinkman apparatus for thin layer, or equivalent.

(h) Chromatographic tank and accessories: Arthur H. Thomas Co., Vine Street at 3rd, Philadelphia, PA. 19105, No. 3106-F05, or equivalent, with metal or glass troughs.

(i) Ultra-violet light source: Four germicidal lamps, 15 watt, 18" long mounted in a metal cabinet 20" x 10" x 10" to accommodate two glass plates.

(j) Gas liquid chromatograph: Consisting of an electron capture detector, power supply, electrometer and 1 mv recorder, on-column injection system, all-glass column in oven controlled to ±0.1° C.

(k) Column: Six feet x four mm id (approximately) packed with 10 percent OV-101 on 100-120 mesh Anakrom ABS, (Analabs Inc., Post Office Box 501, North Haven, Connecticut 06473). The column should be conditioned at 250° C with a nitrogen flow of 100 to 120 ml/min until endrin emerges as a single peak.

(l) Alternate column - 6-ft x 4 mm (approximately) packed with 1.5 percent OV-17 and 1.95 percent OV-210 on 100-120 mesh Chromsorb WHP or equivalent. The column should be conditioned at 250° C. Other equivalent liquid phases and support may be used. (If this column is used, the 6 percent and 15 percent elutions may be combined).

5.001 C. Solvents

Some solvents, sold as suitable for use as received, are available from many manufacturers, and are usually identified as Nanograde or chromatographic grade. All solvents, however, must be tested prior to use to determine whether purification is required. This test is to be performed as outlined on the following page. Those solvents requiring purification must be distilled in an all-glass apparatus. However, if Nanograde or chromatographic grade solvents are found to require purification, they should be returned to the supplier with a request for replacement, since their high cost is predicated upon purity.

(1) *CAUTION*

Ethers (excluding petroleum ether) containing unsafe concentrations of peroxides can detonate when they are distilled or concentrated. No quantity of ether, therefore should be distilled of concentrated before the following test is performed:

"Shake 1 ml of a freshly prepared saturated solution of KI with 9 ml of ether in a 25 ml glass stoppered cylinder. Any yellow color indicates a concentration of peroxide greater than 0.005 percent."

Such a concentration is dangerous, and ether containing this level of peroxide should be discarded, or returned to the supplier with a request for an exchange. Prior to discarding or returning the ether should be deactivated in the following manner:

"Add 30 ml of a 30% (w/v) aqueous ferrous sulfate solution per liter of ether. Use caution, because this reaction may be vigorous if ether contains high concentration of peroxides."

(2) *PURITY TEST*

Electron capture gas chromatography requires the absence of substances causing any detector response from the following test: Place 300 ml of solvent in the Kuderna-Danish Concentrator fitted with a three-ball Snyder column and a calibrated collection tube and evaporate to 5 ml. Inject 5 µl of concentrate into the gas chromatograph using operating conditions described in the paragraph, "Residue Detection Method - Gas Chromatograph." Concentration must not cause recorder deflection greater than 3 mm from base line for 2 to 60 minutes after injection. If thin layer is used for semi-quantitative analysis, 50 µl of the concentrate is spotted on the plate, developed, sprayed and exposed to UV light as described in the paragraph (5.001H), "Thin-layer chromatography." There should be no spots visible.

5.001D. Reagents

(a) Acetonitrile: Practical Eastman Organic Chemicals (our experience has been that it seldom requires purification). If purification is necessary, purify as follows:

To four liters of acetonitrile add 1 ml of H_3PO_4, 30 grams
P_2O_5, a few boiling chips and distill in all glass apparatus
at 81-82° C. DO NOT EXCEED 82° C.

(b) Acetonitrile saturated with petroleum ether: Saturate CH_3CN with petroleum ether (f). A small layer of petroleum ether should just be visible on the CH_3CN.

(c) Eluting solvent, 6 percent: Dilute 60 ml ethyl ether (e) to one liter with petroleum ether (f).

(d) Eluting solvent, 15 percent: Dilute 150 ml ethyl ether (e) to one liter with petroleum ether (f).

(e) Ethyl ether: Reagent or ACS grade. (See Caution under Solvents).

(f) Petroleum ether: 30° - 60°C, boiling range.

(g) Sodium sulfate: Anhydrous granular and anhydrous powder.

(h) Aluminum oxide: Al_2O_3 G available from Warner-Chilicott Laboratories, Instruments Division, 200 South Garrad Blvd., Richmond, California 94801. Al_2O_3-G neutral, available from Merck & Co., Rahway, New Jersey 07065.

(i) Developing Solvents

(1) n-Heptane, commercial or technical grade (no purification required)

(2) n-Heptane, commercial or technical grade, containing 2 percent acetone, reagent grade.

(j) Chromogenic agent: Dissolve 0.100 grams $AgNO_3$ in 1 ml H_2O, add 20 ml 2-phenoxyethanol (Practical, Eastman Organic Chemicals), dilute to 200 ml with reagent grade acetone, add one small drop of 30 percent H_2O_2 and mix. Store in dark over night and decant into spray bottle. Discard after four days.

(l) Standard solutions for thin-layer chromatography.

a. Stock solutions A_1 and A_2 (mixture of aldrin, lindane heptachlor epoxide and methoxychlor): Weigh 0.1 g of each pesticide into same 10 ml glass stoppered volumetric flask (A_1). Repeat with 0.05 g of each into a second volumetric flask (A_2). Dissolve in ethyl acetate, dilute to 10 ml and mix. One μl of each solution contains 10 μg and 5 μg, respectively, of each pesticide.

b. Stock solutions B_1 and B_2 (mixture of BHC, DDE, DDD, DDT, dieldrin, and endrin): Prepare solutions of 10 and 5 $\mu g/\mu l$ as in (a).

c. Dilutions of stock solutions: From the stock solutions prepare dilutions containing 0.2, 0.1, 0.05, 0.02, 0.01, 0.005 and 0.002 $\mu g/\mu l$.

(k) Individual Standards: Separate standards of each insecticide should be prepared at 0.1 $\mu g/\mu l$ concentration so that the migration of each insecticide can be determined and the insecticide can be identified in the mixtures.

(l) Gas-liquid chromatography: The individual standards from "(k)" are diluted so that a 5 μl injection will contain approximately 0.25 nanogram of heptachlor epoxide and will give approximately 50 percent of full scale deflection on the recorder. The concentrations of all other insecticides should be adjusted accordingly: Lindane and BHC should be approximately 0.5 of the heptachlor epoxide; dieldrin, endrin and DDE should be 1.5 times; DDD should be about 2 times, DDT about 4 times and methoxychlor about 8 times. This is approximate, and must be determined for each gas-liquid chromatograph used.

(m) Gas liquid chromatography mixture standards: After retention time and response have been determined for the separate insecticides, prepare mixtures so that the peaks will not interfere with each other, i.e., BHC, DDE, DDD and methoxychlor in one solution; lindane, aldrin, heptachlor epoxide, dieldrin and endrin in another. The concentrations should be such that a 5 μl injection produces a 1/2 scale recorder deflection.

(a) Florisil: 60/100 Pesticide Residue (PR) grade, activated at 1250°F (650°C) available from the Floridin Co. When 1250° F activated, Florisil is obtained in bulk, transfer immediately after opening to ca 1 pt (500 ml glass jars, or bottles, with glass-stoppered or foil-lined, screw-top lids, and store in dark). Heat ≥ 5 hours at 130° C before use, store at 130° C in glass-stoppered bottles or in a desiccator at room temperature and reheat at 130° C after two days.

5.001E. Standardization of Florisil

(a) *REAGENTS*

(1) Indicator: Dissolve 1 g of phenolphthalein in ethyl alcohol and dilute to 100 ml.

(2) Ethyl alcohol, neutralized to phenolphthalein.

(3) Lauric acid solution: Dissolve 10.000 g lauric acid in distilled hexane and dilute to 500 ml.

(4) 0.05N NaOH: Dissolve 2.000 g sodium hydroxide in distilled water and dilute to one liter.

Lauric Acid: Sodium Hydroxide ratio: Pipet 10.0 ml lauric acid solution (200 mg) into a 125 ml erlenmeyer flask. Add 50 ml of neutralized ethyl alcohol, three drops of indicator and titrate with 0.05N NaOH to a permanent end-point. Calculate mg lauric acid per ml 0.05N NaOH.

(b) *PROCEDURE*

(1) Transfer 2.000 g activated Florisil to a 25 ml standard taper Erlenmeyer flask. Add 20 ml lauric acid solution (400 mg), stopper, and shake occasionally for 15 minutes.

(2) Let adsorbent settle and pipet 10.0 ml of supernatant into 125 ml Erlenmeyer flask. Avoid inclusion of any Florisil.

(3) Add 50 ml neutral ethyl alcohol and three drops of indicator solution; titrate with 0.05N NaOH to a permanent end-point.

(4) Calculate amount of lauric acid absorbed on Florisil, (lauric acid value), as follows: mg Lauric Acid/g Florisil = (200 - (ml required for titration x mg lauric acid/ml 0.05N NaOH.)

A lauric acid value of 110 (LAV) is the acceptable value; i.e., 20 g of Florisil would fill a 22mm id column to a depth of 110 mm. To obtain the equivalent quantity of Florisil, divide 110 by the lauric acid value for that batch and multiply by 20: $\frac{110 \times 20}{LAV}$ = g Florisil required.

The columns are prepared as in the clean up technique, and prewashed with 100 ml petroleum ether. . ml aliquot of mixed pesticides containing 0.2 μg lindane, 0.4 μg heptachlor epoxide, 0.6 μg dieldrin and 0.6 μg endrin is placed on the column. The columns are eluted as in the clean up technique. The eluates are concentrated, transferred to 25 ml volumetric flasks and made to volume with petroleum ether. One ml of the mixed pesticides is also diluted to 25 ml with petroleum ether in a volumetric flask. Inject 5 μl of the standard and of the two eluates into the gas chromatograph. The recovery of the pesticides when (6% and 15% eluates) compared to the standard must be at least 95 percent and lindane and heptachlor epoxide must be in the 6 percent elution while dieldrin and endrin must be in the 15 percent elution.

5.001F. Determination

5.001 F.1. Sample Preparation

(a) *Fatty Tissue*

Pass chilled sample through food chopper twice. If dry ice is available, add small quantities to fat to maintain a low temperature. Plug a powder funnel moderately tight with glass wool; place approximately 100 g of the comminuted fat in the funnel; position the funnel in a beaker and render at 125°C until the fat ceases to drop.

(b) *Muscle Tissue*

Pass sample through food chopper three times. Grind suitable quantity with anhydrous Na_2SO_4 to combine with moisture in sample. Transfer granular mixture to centrifuge bottle, add 100 ml petroleum ether, shake vigorously and centrifuge about 5 minutes at about 1500 rpm. Pour off solvent layer into beaker and re-extract residue twice with 50 ml portions of petroleum ether. Evaporate combined extracts to obtain fat.

All chlorinated hydrocarbon residues are reported on the basis of the rendered or extracted fat.

5.001 F2. Acetonitrile Partitioning

(a) Weigh 5 g of melted fat into a 50 ml beaker, add 10 ml of petroleum ether and transfer to a 125 ml separatory funnel.

(b) Use an additional 15 ml in small portions to rinse the beaker for a quantitative transfer of the fat.

(c) Add 25 ml of acetonitrile saturated with petroleum ether and shake vigorously for 1 minute.

(d) Let layers separate (adequate time must be allowed to obtain a good separation).

(e) Drain the bottom (acetonitrile) layer into a 500 ml separatory funnel containing 300 ml of 4 percent Na_2SO_4 and 100 ml of petroleum ether.

(f) Extract the petroleum ether solution in the 125 ml separatory funnel with 3 additional portions of acetonitrile saturated with petroleum ether, shaking vigorously 1 minute each time. Combine all extracts in the 500 ml separatory funnel.

(g) Stopper, invert the 500 ml separatory funnel, vent pressure, and shake gently 1 minute to transfer the pesticides to petroleum ether.

(h) Let layers separate cleanly and discard lower aqueous layer.

(i) *Caution:* occasionally excessive pressure will build up. Wash the petroleum ether in 500 ml separatory funnel with two 50 ml portions of 4 percent Na_2SO_4, stopper invert and after each addition vent.

(j) Discard washings and draw off petroleum ether layer through a 2 inch column of anhydrous granular Na_2SO_4 in the filter tube into a 250 ml erlenmeyer flask.

(k) Rinse the separatory funnel and the column with two 10 ml portions of petroleum ether.

(l) Evaporate combined extract and rinses to ca 10 ml in a Kuderna-Danish or alternate concentrator.

5.001F3. Florisil Column Chromatography

(a) Prepare 22 mm id florisil column, containing 100 mm after packing of activated florisil topped with about 1/2 inch of anhydrous sodium sulfate powder (110 mm should pack to 100 mm).

(b) Prewet column with 40-50 ml petroleum ether.

(c) Transfer petroleum ether extract to column, letting it pass through the column at a rate not to exceed 3 ml/min (optimum rate is approximately 2.5 ml/min).

(d) When the last of the petroleum ether has sunk into the column, change receivers and elute with 110 ml of 6 percent ethyl ether in petroleum ether at the same rate.

(e) Change receivers and elute with 110 ml of the 15 percent ethyl ether in petroleum ether.

(f) Concentrate each eluate to 5 ml using the Kuderna-Danish or alternate concentrator. Transfer each eluate quantitatively to a 25 ml volumetric flask and make to volume with petroleum ether. When the elution from the florisil column is held to the low rate specified, the insecticides are eluted quantitatively from the column and both eluates are suitable for thin-layer or gas-liquid chromatography.

(g) First eluate (6 percent) contains aldrin, BHC, DDE, DDD(TDE), o,p-DDT and p,p'-DDT, heptachlor, heptachlor epoxide, lindane and methoxychlor.

(h) Second eluate (15 percent) contains dieldrin and endrin.

5.001G. Residue Detection Method Gas Chromatography

Operating conditions for 10 percent OV-101 or the mixed phase column. Injection temperature 225° C, column temperature 185° C to 200° C, detector temperature 210° C (maximum if H^3 detector is used), carrier gas flow 120 ml nitrogen/min. Detector voltage, instrument settings must be determined for each chromatograph to obtain the maximum sensitivity.

Check the linearity of the system. Determine the individual retention times of the insecticides. *Make calculations only from peaks that are in the linear range.*

Inject a suitable aliquot (3-8 µl) of the eluates from the 25 ml volumetric flask into the chromatograph using a 10 µl syringe. If peaks are out of the linear range, re-inject using a smaller aliquot or dilute to bring the response into the linear range. Tentatively identify residue peaks on the basis of retention time. Measure areas under the peak or peaks from the unknown and compare to the areas obtained from known quantity of the standard insecticide. For most accurate measurement, unknown and standards should be of similar size (i.e. ±15%) and in the linear range of the detector used.

Chromatograph the standard pesticide immediately after the sample. Alternatively, it is possible to use only peak heights with a slight loss in accuracy, but good judgement is required, and it is very important that all measurements be in the linear range of the detector.

5.001H. Thin-Layer Chromatography

(a) *Preparation of adsorbent layer* (TLC plates are commercially available)

Select five 8 x 8 inch double strength window glass plates of uniform width and thickness and smooth off the corners and edges with a file or other suitable instrument. Before coating, wash the plates in hot soapy water and

thoroughly rinse with distilled water. Press the plates snugly into position on the mounting board which has a retaining ledge on one side and one end. The plastic board is mounted so that its long side with raised ledge faces the operator while the short side with ledge is to the right of the operator. Before coating, the surface of the plates are wiped with a few ml of 95 percent ethanol on a tissue to remove fingerprints or other adhering material.

Position the applicator (set at 250 microns), trough open, with the left edge 1/4 inch in from the edge of the first plate to be coated.

To coat 5 plates, weigh 30 g Al_2O_3-G into a 250 ml standard taper Erlenmeyer flask. Add 50 ml distilled water, stopper flask and shake moderately for 45 seconds. Violent shaking produces bubbles resulting in a "pockmarked" layer.

NOTE: Suspensions which contain adsorbent with binders set rapidly and the entire procedure from the preparation of the slurry to the final coating must be completed within 2 minutes.

After shaking, immediately pour the slurry into the applicator chamber. Rotate the chamber by turning the handle through 180°. After a few seconds, the slurry begins to flow out of the exit slit. Grasp the applicator with both hands and pull it manually with a steady motion across the series of plates. Approximately 5 seconds are required for the actual coating procedure. Immediately after application, tap the edge of the mounting board or shake the entire board gently to smooth out slight ripples or imperfections in the wet coating.

Let coated plates dry in position on mounting board for 15 minutes. Then dry plates in a forced draft oven at 80° C for 30 minutes. Remove plates and cool.

Examine the plates carefully in transmitted and reflected light for imperfections or irregularities in the coating. Plates should be discarded if extensive rippling or mottling of the layer is observed.

Five more 8" X 8" plates may be prepared while the first set is drying. Be sure the applicator is thoroughly cleaned and dried before reusing. The 10 coated and dried plates may be prewashed immediately.

(b) *Prewashing or Adsorbent Layer* (Not necessary for commercial plates)

Scrape 1/2 inch of adsorbent off the one edge of the plate at 90° to direction of application with a razor blade. Then pour 15 ml 50 percent aqueous acetone into a metal trough inside the chromatographic tank. Cut out a 3/4 inch x 8 inch strip of Whatman No. 1 filter paper, wet with solvent and place over the scraped off portion with 1/4 inch overlapping the adsorbent layer. Place the plate in the chromatographic tank, seal tank with masking tape if necessary and develop with 50 percent aqueous acetone to within 1-1/2 inches from the top of the plate (75-90 minutes). Remove the plate from the tank, remove filter paper wick, invert the plate, and dry in the hood for 5 minutes. Dry the plate at 80° C for 45 minutes. Remove plate from oven, cool and store in desiccator until needed. The prepared plates should be used within one week after preparation.

(c) *Sample Spotting*

A pencil mark is made 1-1/2 inches from the bottom of the plate (edge with adsorbent removed) at both sides. An imaginary line between the two points indicates the sample spotting or origin "line." Draw a line (which removes the coating) completely across the plate 5-1/2 inches from the bottom edge. This line represents the solvent front after development. On the lower edge of the adsorbent starting 3/4 inch in from the left edge of the plate make 13 marks with a pencil at 3/8 inch intervals. (Fewer marks with greater intervals may be used if desired). The marks serve as horizontal guides to sample application. The identity of samples and standards may be etched directly into the adsorbent layer above the solvent front line and in alignment with these marks.

The imaginary spotting "line" is actually a shadow line cast by a strong light source from a wooden ruler supported 1 inch above the plate. The ruler shadow is aligned on the two 1-1/2-inch marks on either edge of the plate. The shadow line and 18 marks respectively serve as vertical and horizontal guides for sample application.

For optimum semi-quantitative estimation, adjust aliquot of sample spotted to give residue spot within the range 0.005 μg to 0.1 μg. Concentrations of standards and standard mixtures spotted should be 0.002, 0.005, 0.01, 0.02, 0.05, 0.1, and 0.2 μg. Sample spots greater than 0.2 μg are difficult to estimate quantitatively and less than .005 μg may be difficult to distinguish. The volume of sample extract spotted should not exceed 10 μl if possible and spotting should be done repeatedly with a 1 μl Kontes spotting pipet, or equivalent. Care should be taken not to disrupt the surface of the absorbent. Standard and sample solutions should be spotted with the same pipet, but the pipet must be cleaned between spottings. For the best results keep the size of spotted sample as small as possible. All 6-percent extracts are spotted on one plate and 15 percent extracts are spotted on another plate.

Spot standard solutions of pesticides (mixtures A&B or single compounds) in different positions on the same plate. The choice of pesticides to be used for identification may be governed by the pesticide residues to be expected in the sample examined. For semi-quantitative estimation, varying amounts of knowns may be chromatographed from spots adjacent to samples.

(d) *Development, Spraying and Exposure of Plates*

1. *Development*

Place liners and trough in tank. Presaturate liner by pouring 75 ml of the appropriate developing solvent into bottom of tank prior (30 minutes or longer) to developing plate. Presaturation decreases development time and improves uniformity of R_f values.

For plates spotted with 6 percent extracts, pour 50 ml n-heptane into the trough. Place the lower edge of the plate in the trough (a wick may be necessary) with the top of the plate leaning against the side of the tank. Place the glass cover plate on the tank and seal with masking tape.

For plates spotted with 15 percent extracts use heptane-acetone (98+2) as developing solvent.

When the solvent front just reaches the pencil line 10 cm above the spotting "line," remove the plate and dry in hood for 5 minutes.

2. *Spraying*

Support plate on one side and spray fairly heavily with the chromogenic reagent, using lateral motions of the spray bottle perpendicular to the direction of solvent flow.

Spray until plate appears translucent or soaked with reagent. Underspraying will result in poor sensitivity. After spraying, dry the plate in the hood for 15 minutes, then place immediately under ultraviolet light source.

3. *Exposure* (Warning! Protect eyes from ultraviolet light)

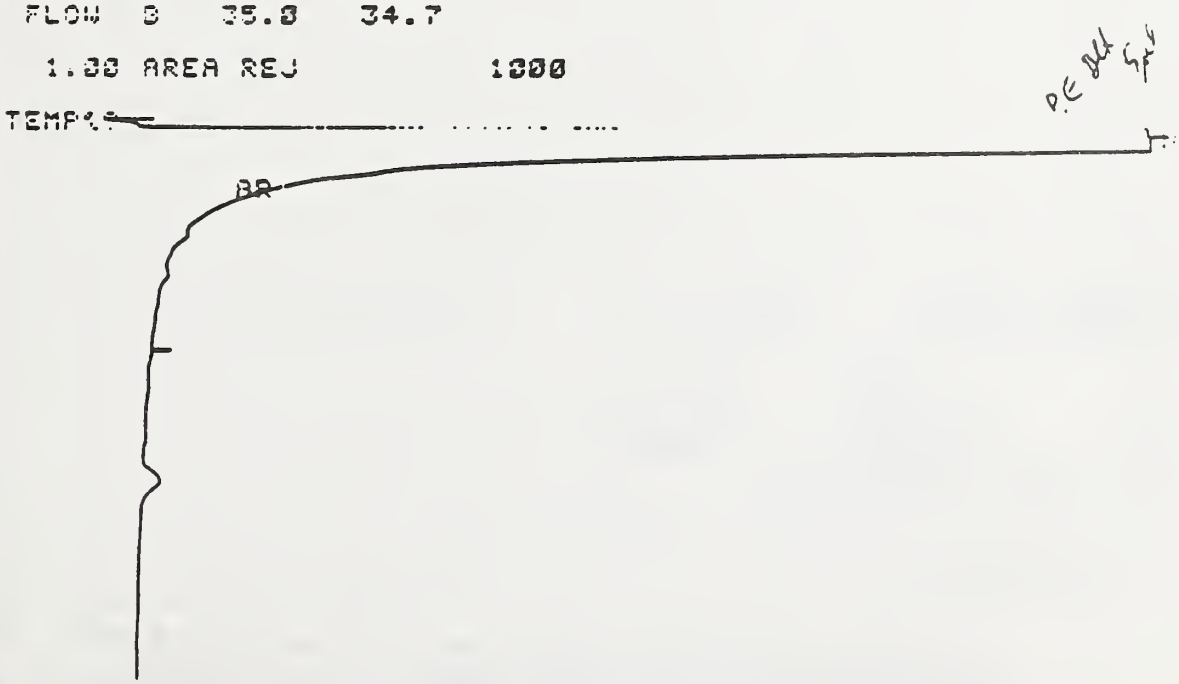
Expose the plate to ultraviolet light until the spot for the standard of lowest concentration appears. Five nanogram quantities of most of the chlorinated organic pesticides should be visible after 15-20 minutes exposure. Exposure times in excess of 30 minutes will not harm the plates. For best results place plates 3" from the bottom edge of the germicide tubes.

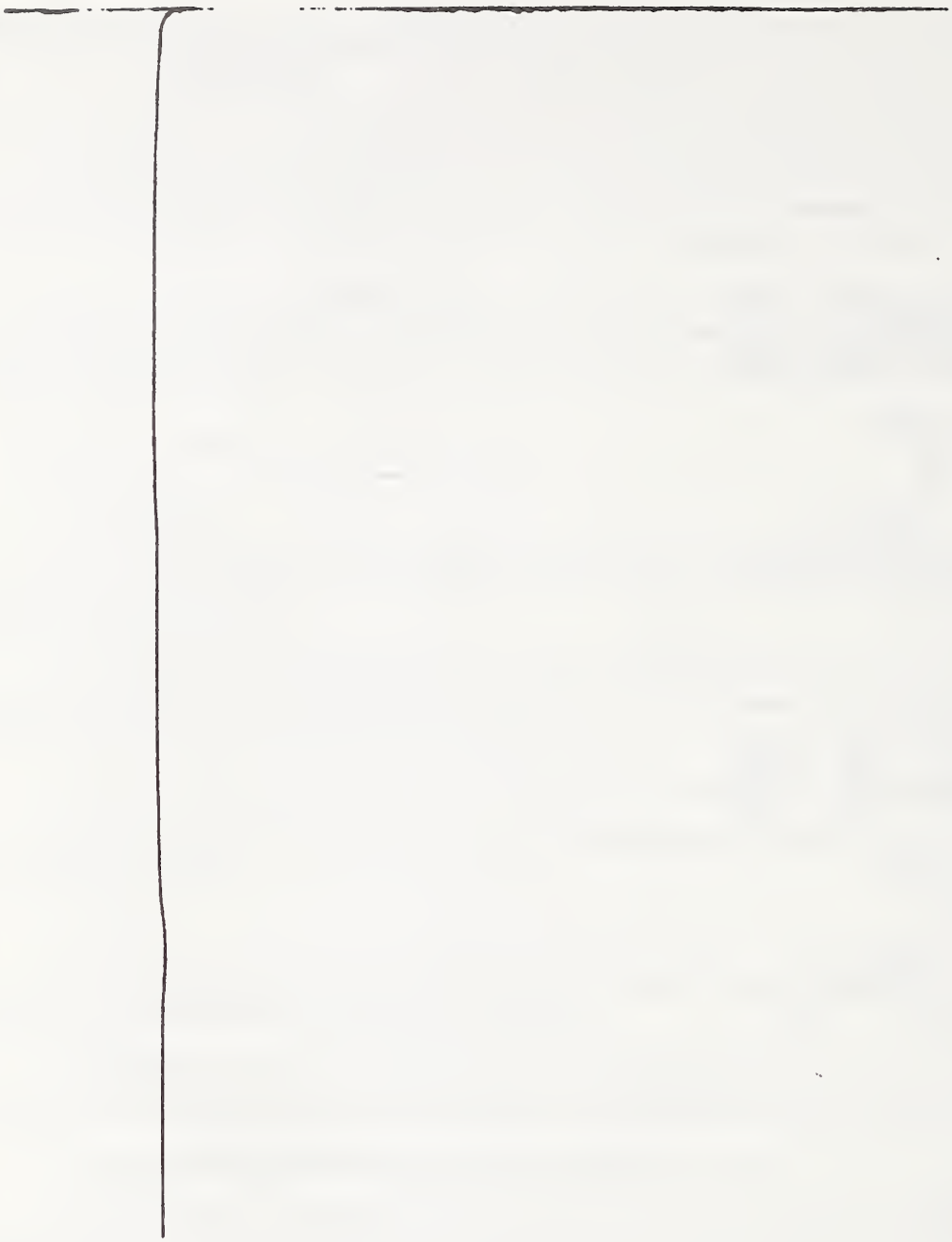
Reference

Official Methods of Analysis of the Association of Official Analytical Chemists, 12th Edition.

ATTACHMENT #7

```
TEMP1      250   100   100
TIME1        25.00
INJ TEMP   275   220   220
FID TEMP   275   225   225
AUX TEMP   350   300   300

CHT SPD      1.00
ZERO        10.0
ATTN 2^      6
AUX SGNL     +D
SLP SENS     0.30
AREA REJ      1000000
FLOW  A      0.0      0.0
FLOW  B     35.0     34.7

  1.00 AREA REJ            1000


TEMP1      250   100   101
TIME1        25.00
INJ TEMP   275   220   220
FID TEMP   275   225   225
AUX TEMP   350   300   300

CHT SPD      1.00
ZERO        10.0
ATTN 2^      6
AUX SGNL     +B
SLP SENS     0.30
AREA REJ      1000000
FLOW  A      0.0      0.0
FLOW  B     35.0     34.7

  1.00 AREA REJ            1000
```

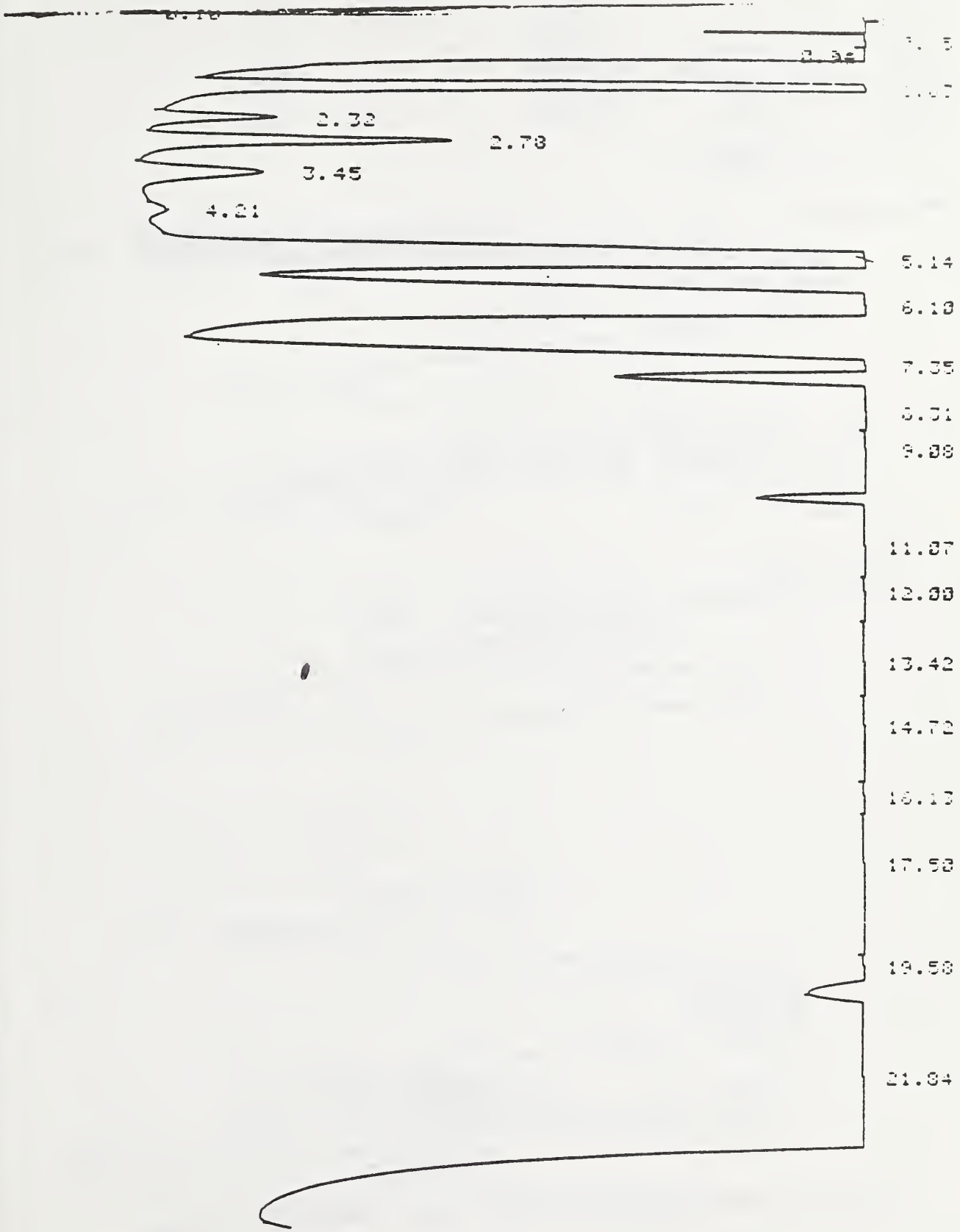




HP RUN # 75 AUG/27/79 TIME 08:51:18
NO PEAKS IN WDOS

RT	AREA	AREA %
3.15	20520003	100.000

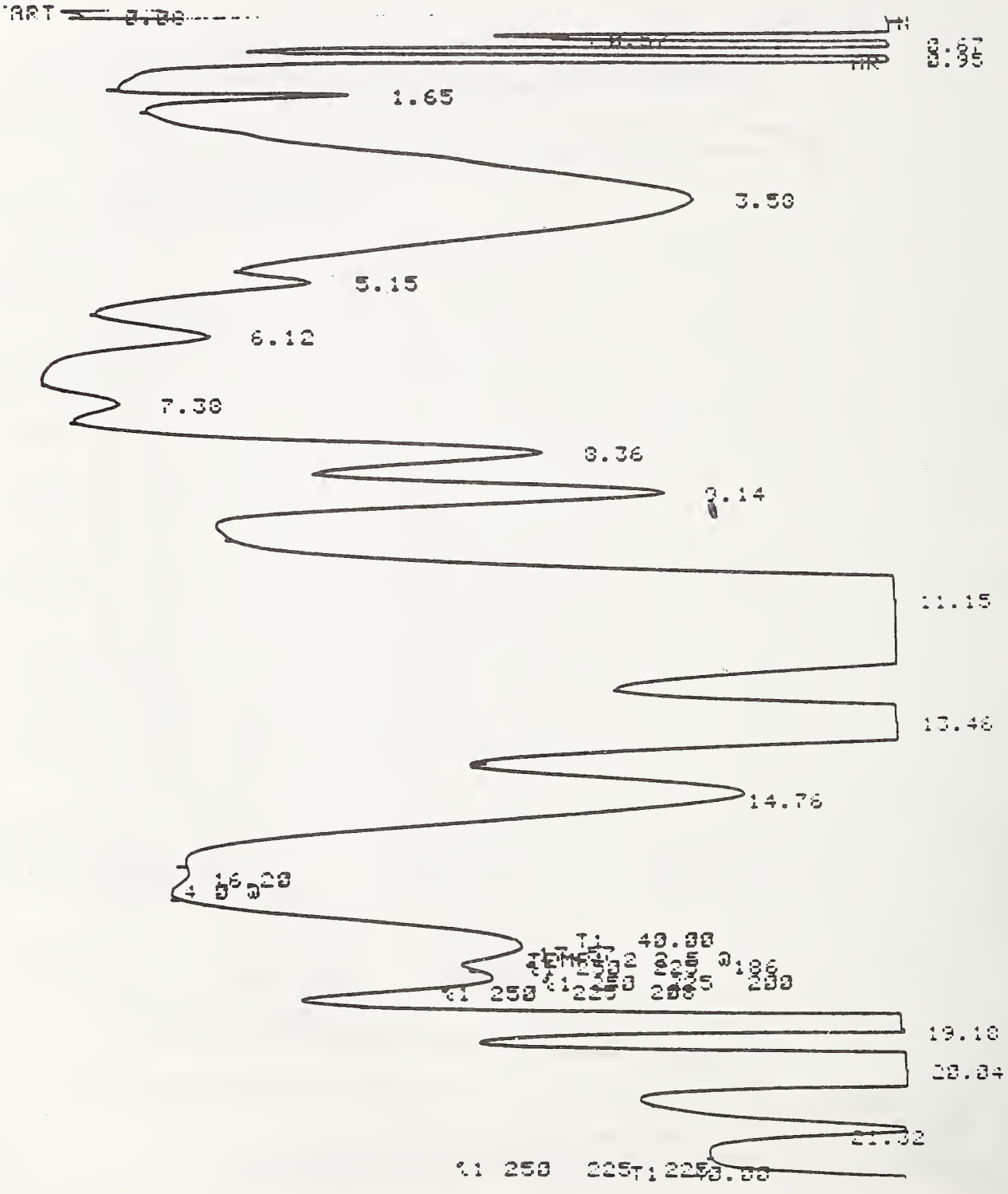
DIL FACTOR: 1.0000 E+ 0

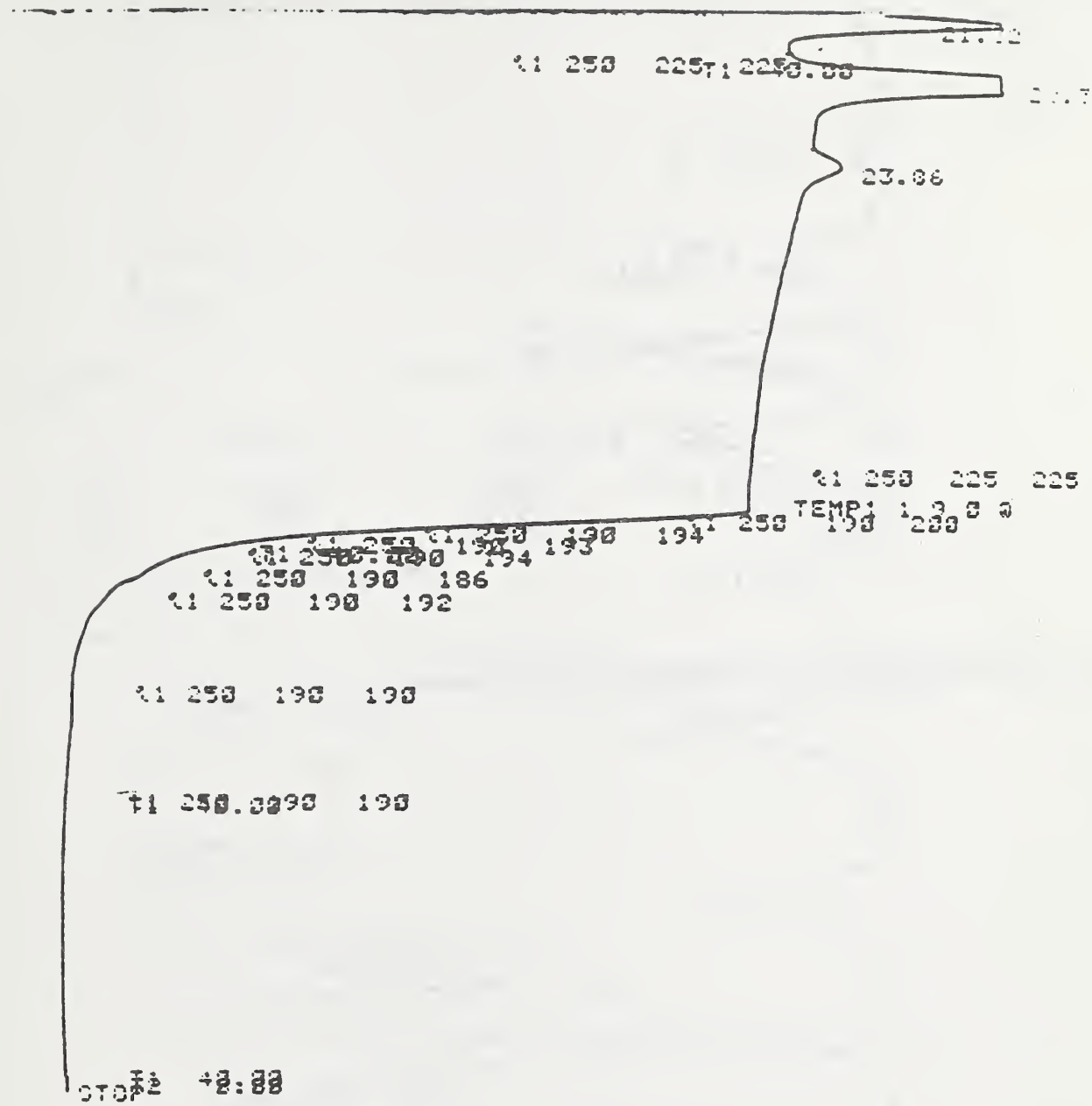


HP RUN # 70 AUG/27/79 TIME 09:22:00

RT	END RT	AREA	CAL #	AMT
[illegible]	[illegible]	23000	5	0.060
[illegible]	[illegible]	58770	(R) 1	0.155
[illegible]	[illegible]	171000	3	0.000
[illegible]	[illegible]	2455200	3	7.000
3.42	13.12	5654000	12	13.301

AL FACTOR: 1.0000 E+ 0

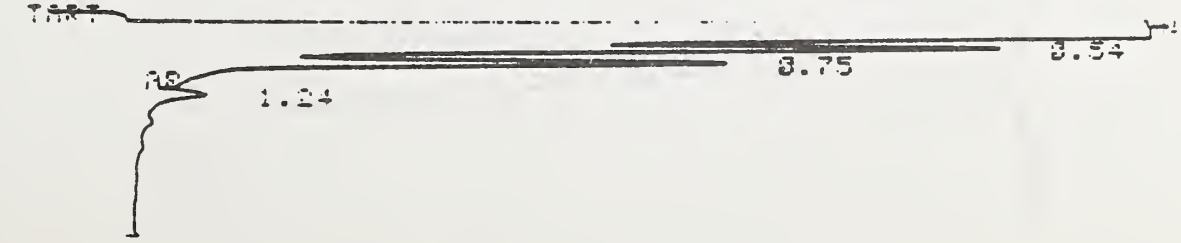


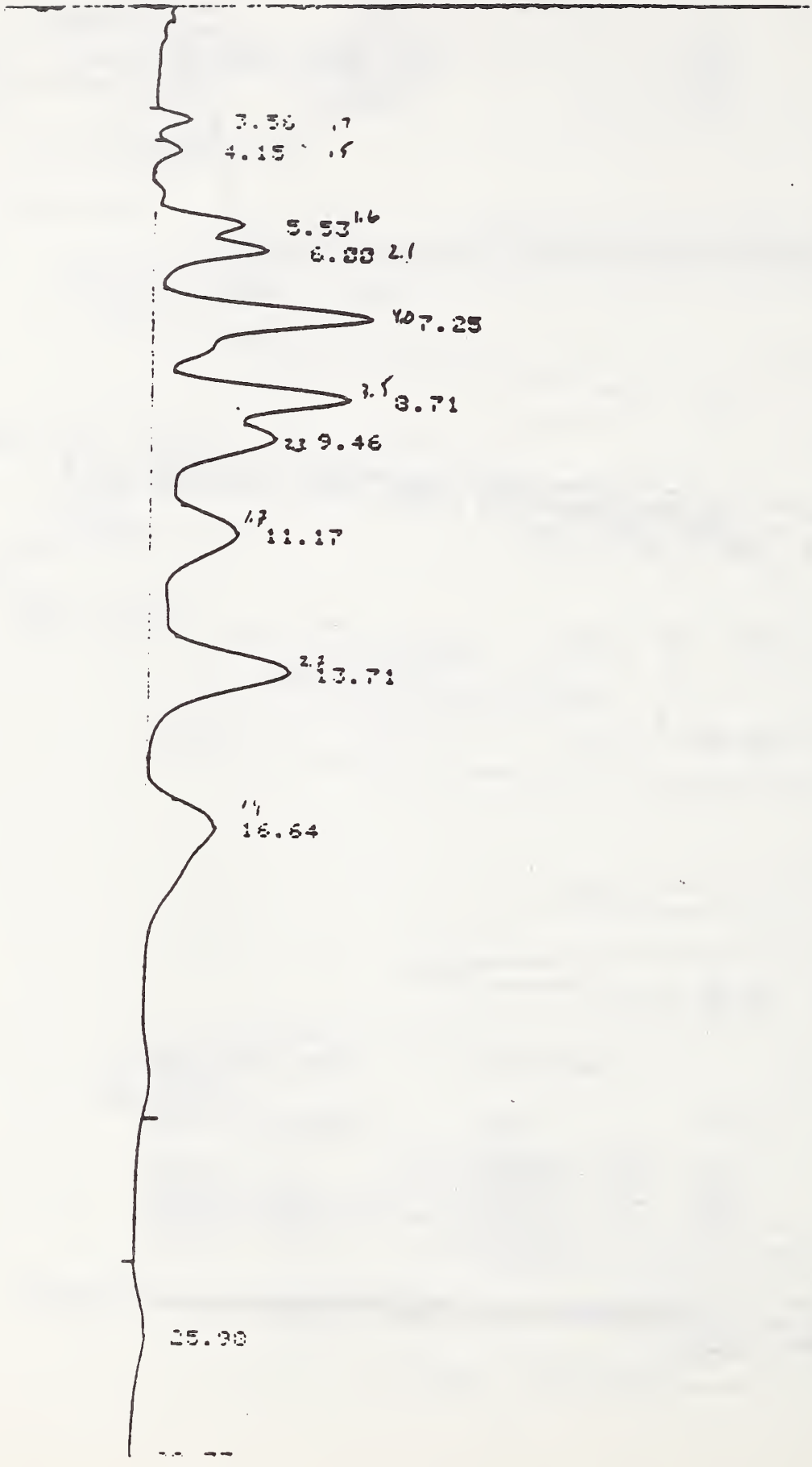


HP RUN # 77 AUG/27/79 TIME 09:53:00
COTD

RT	EXP RT	AREA	CAL #	AMT
5.15	5.27	73900	7	0.208
6.12	6.27	40760	8	0.134
7.30	7.22	11080	9	0.046
9.14	9.31	151200	11	0.478

TOTAL

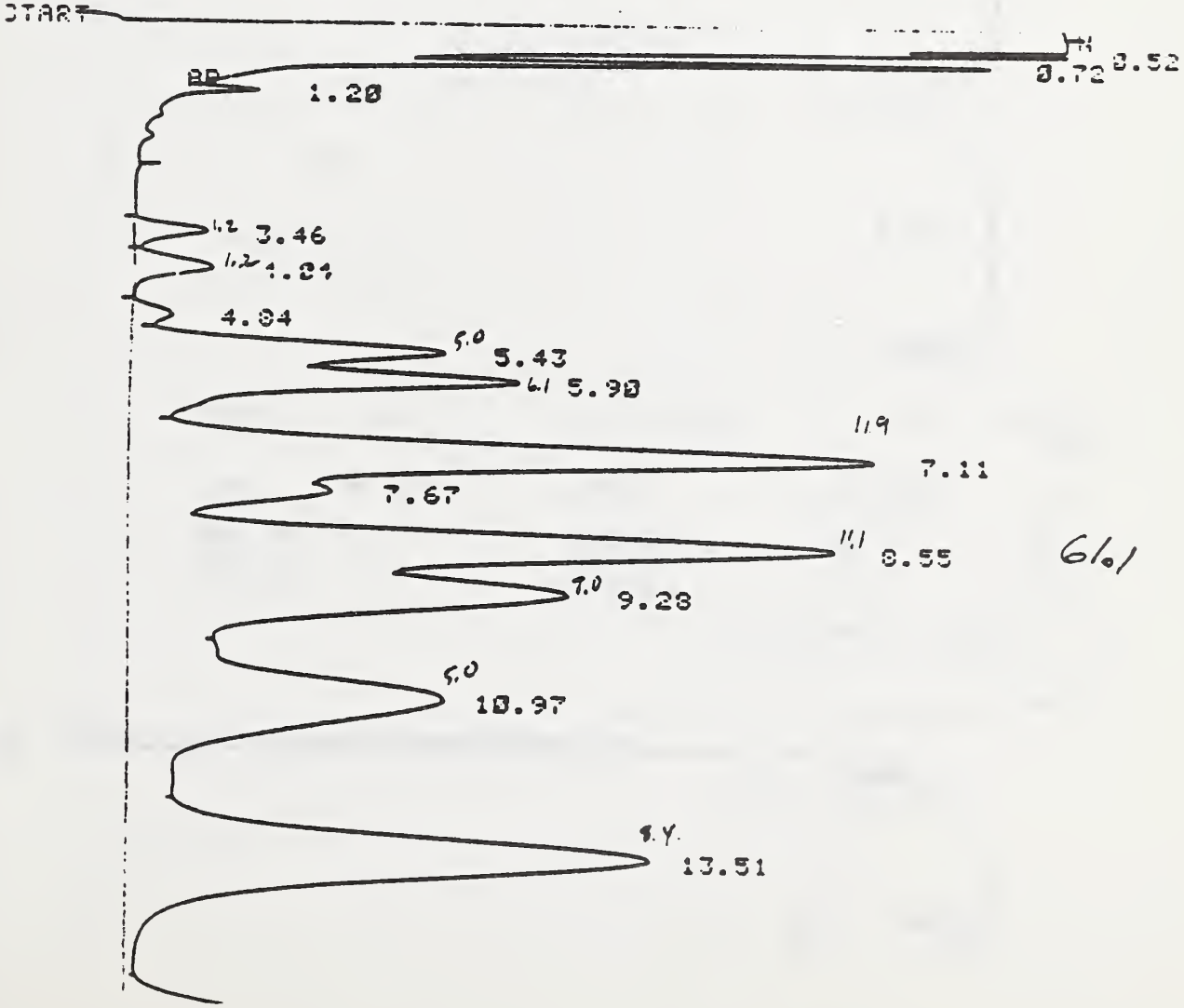


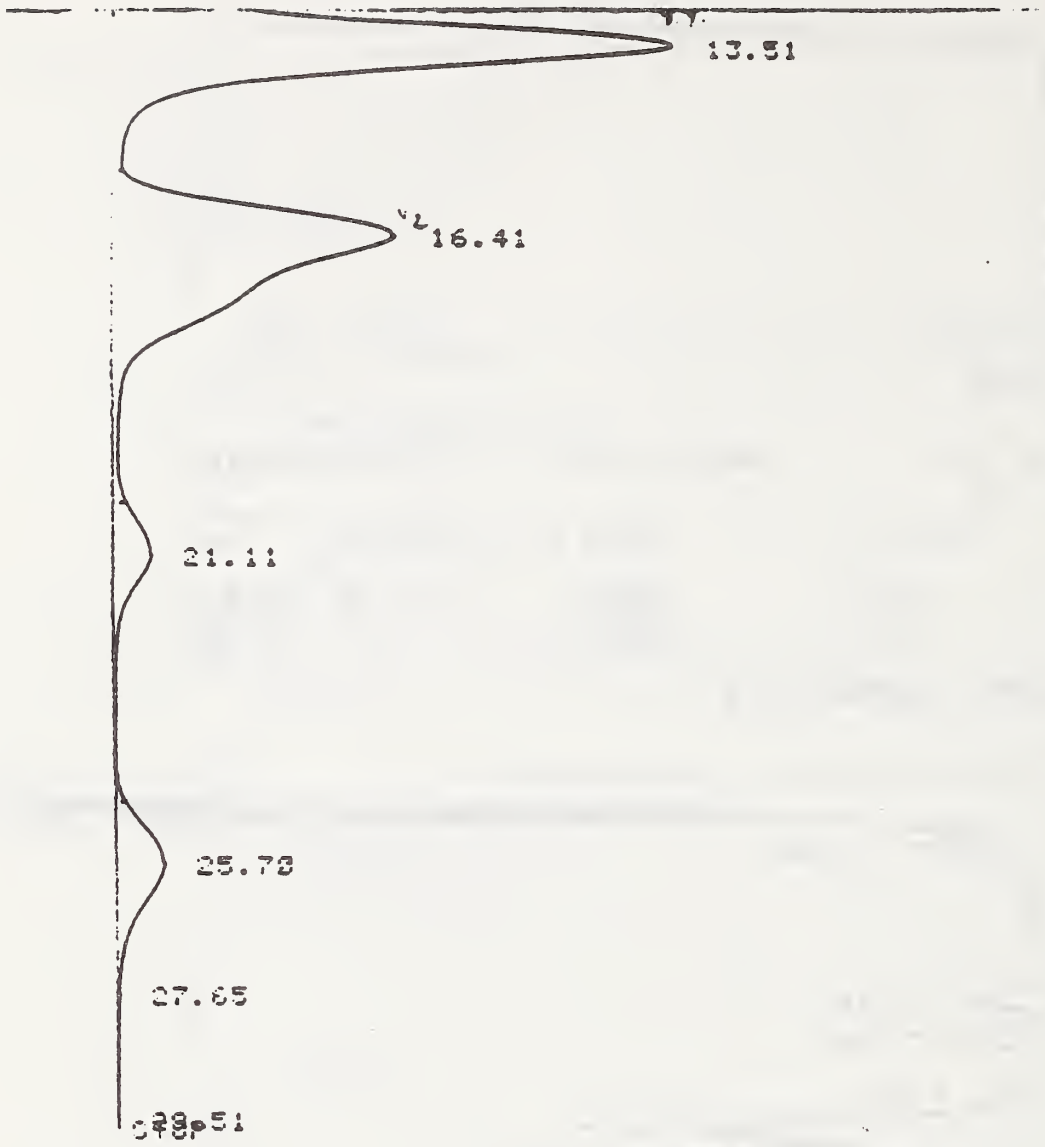

3.56
4.15
5.53
6.88
7.25
8.71
9.46
11.17
13.71
16.64
25.98

HP RUN # 70 AUG-27-79 TIME 10:34:03
ESTD

RT	EXP RT	AREA	CAL #	AMT
4.15	4.17	3906	6	0.013
7.25	7.22	90700	9	0.348
9.46	9.31	60890	11	0.193

DIL FACTOR: 1.0000 E+ 0

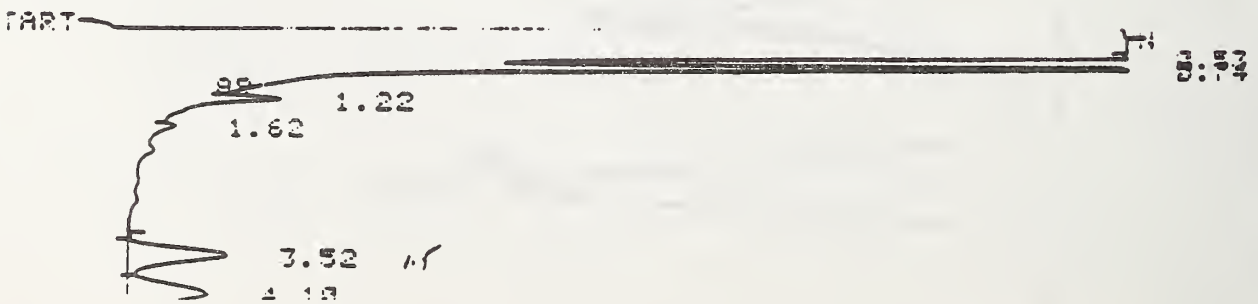


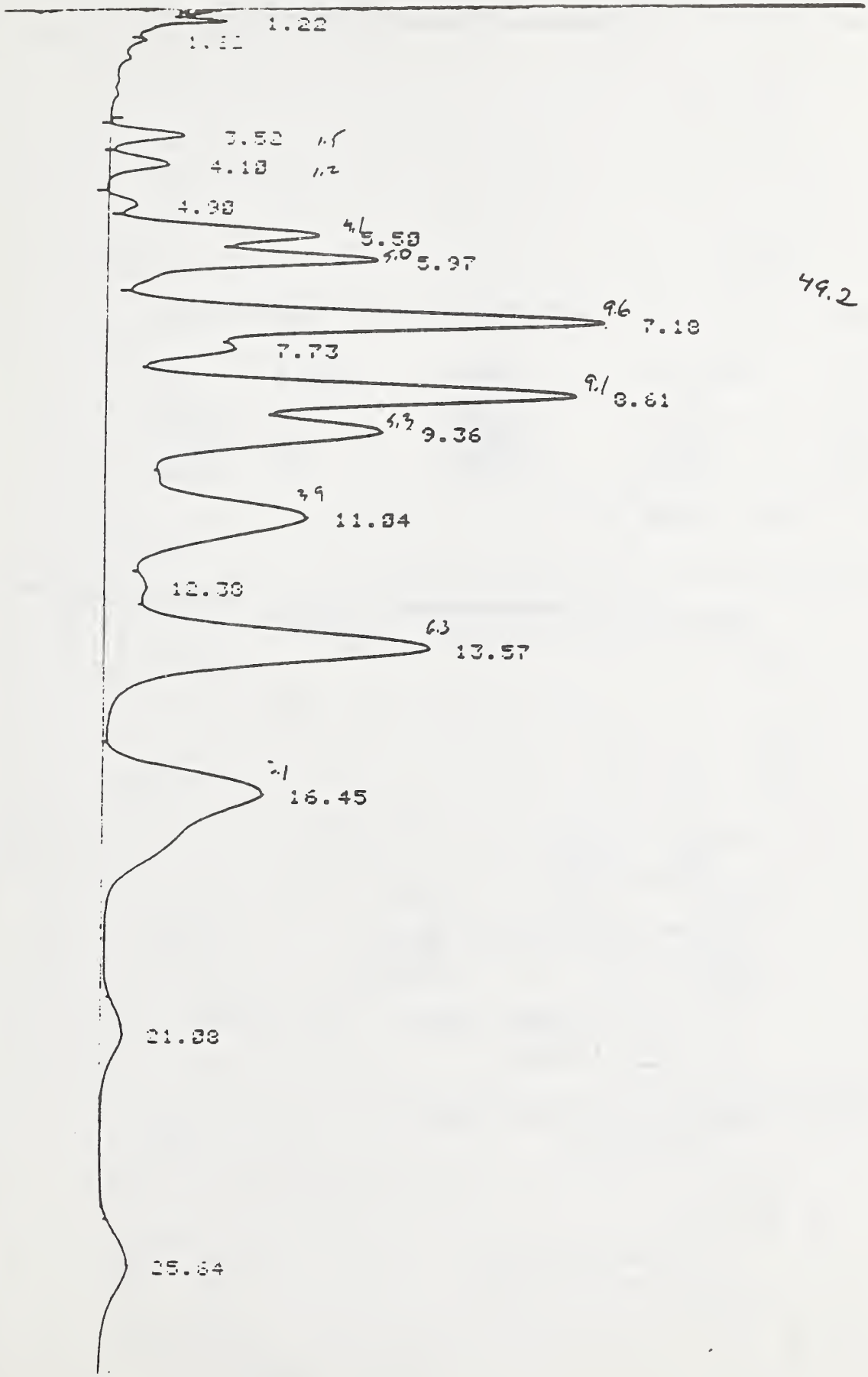


RUN # 79 AUG/27/79 TIME 11:10:05
STD

RT	EXP RT	AREA	CAL #	AMT
7.11	7.22	181000	9	0.695
7.67	7.83	39510	10	0.186
9.28	9.31	146000	11	0.464

IL FACTOR: 1.0000 E+ 0

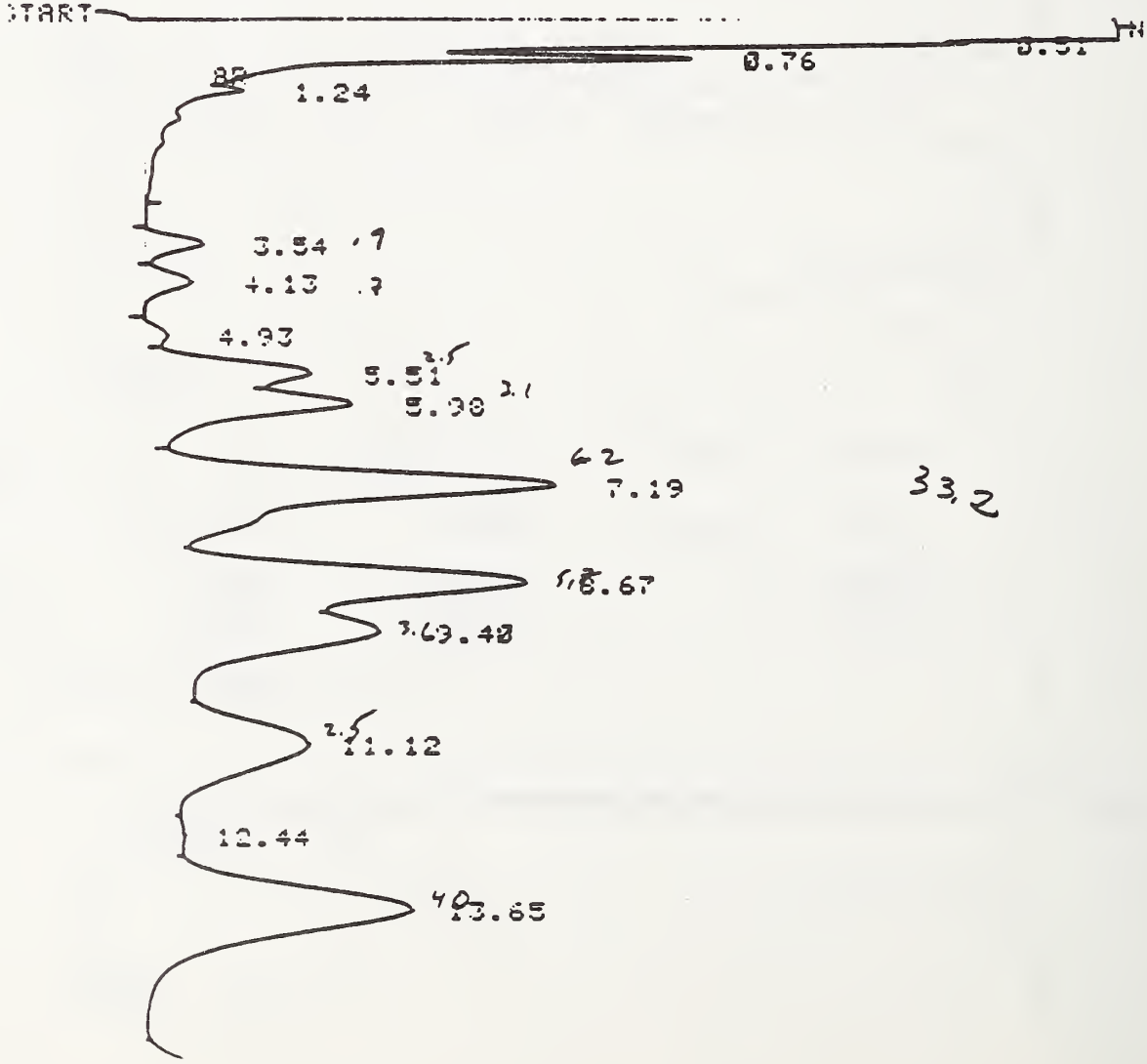


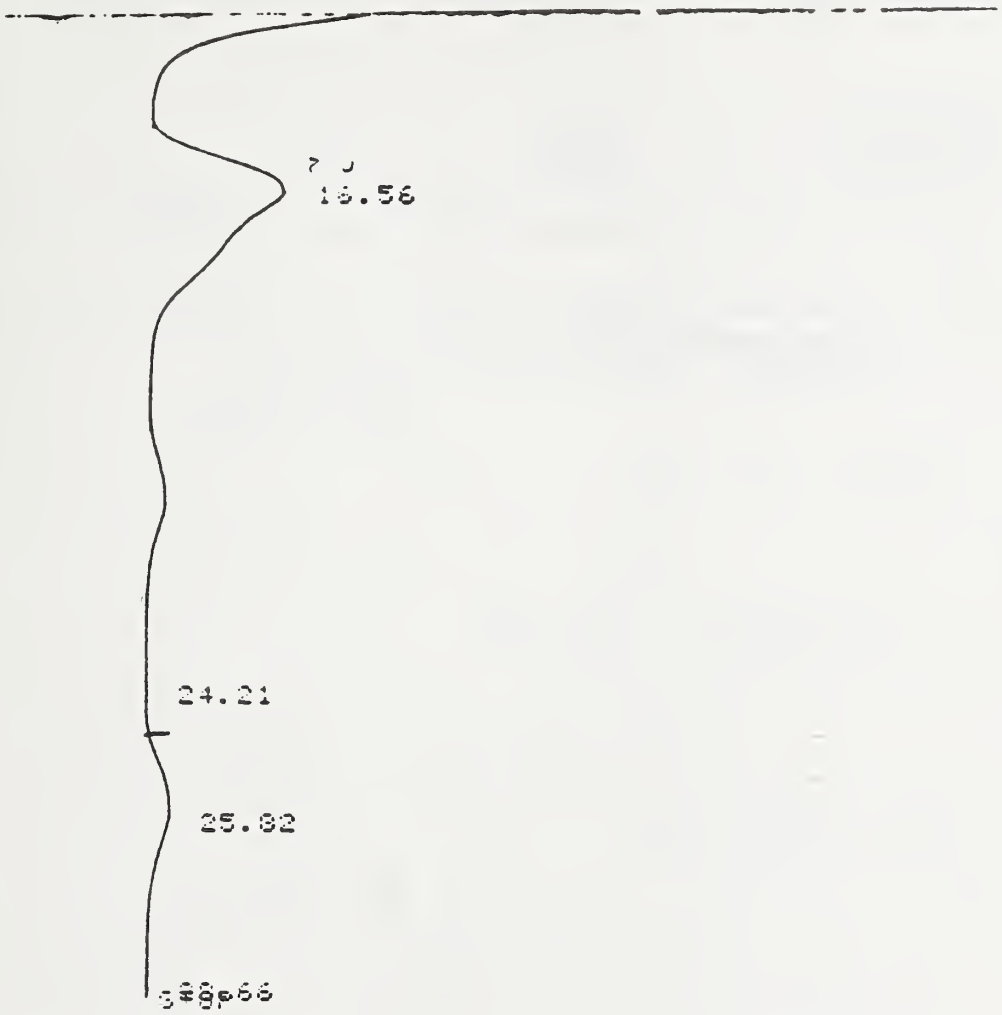

1.22
3.52
4.10
4.38
5.58
5.97
9.6
7.18
7.73
9.1
8.61
9.36
11.84
12.38
13.57
16.45
21.88
25.84
49.2

HP RUN # 88 AUG/27/79 TIME 11:40:45
ISTD

RT	EXP RT	AREA	CAL #	AMT
4.18	4.17	11590	6	0.022
7.18	7.22	146900	9	0.564
7.73	7.83	31230	10	0.147
9.36	9.31	113100	11	0.358

DIL FACTOR: 1.0000 E+ 0

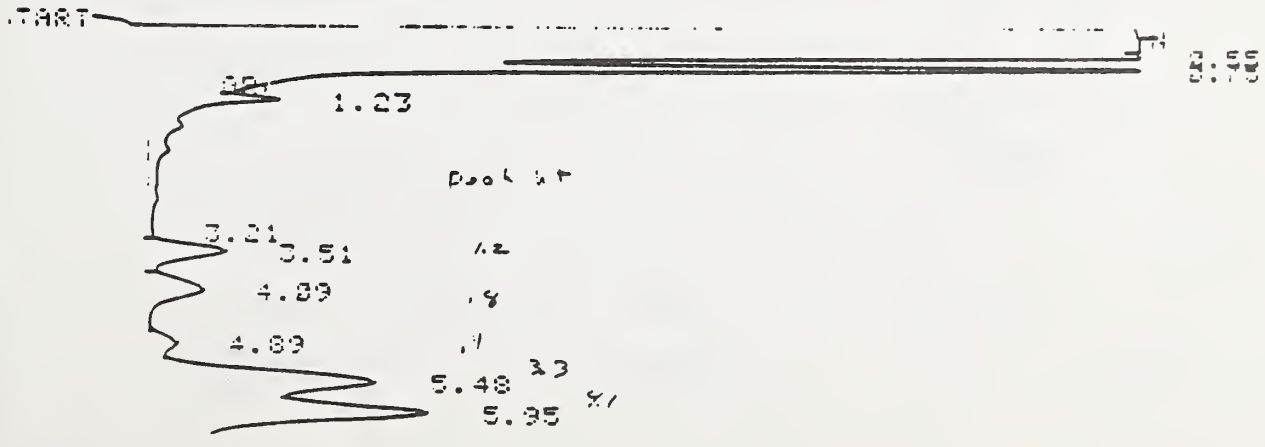


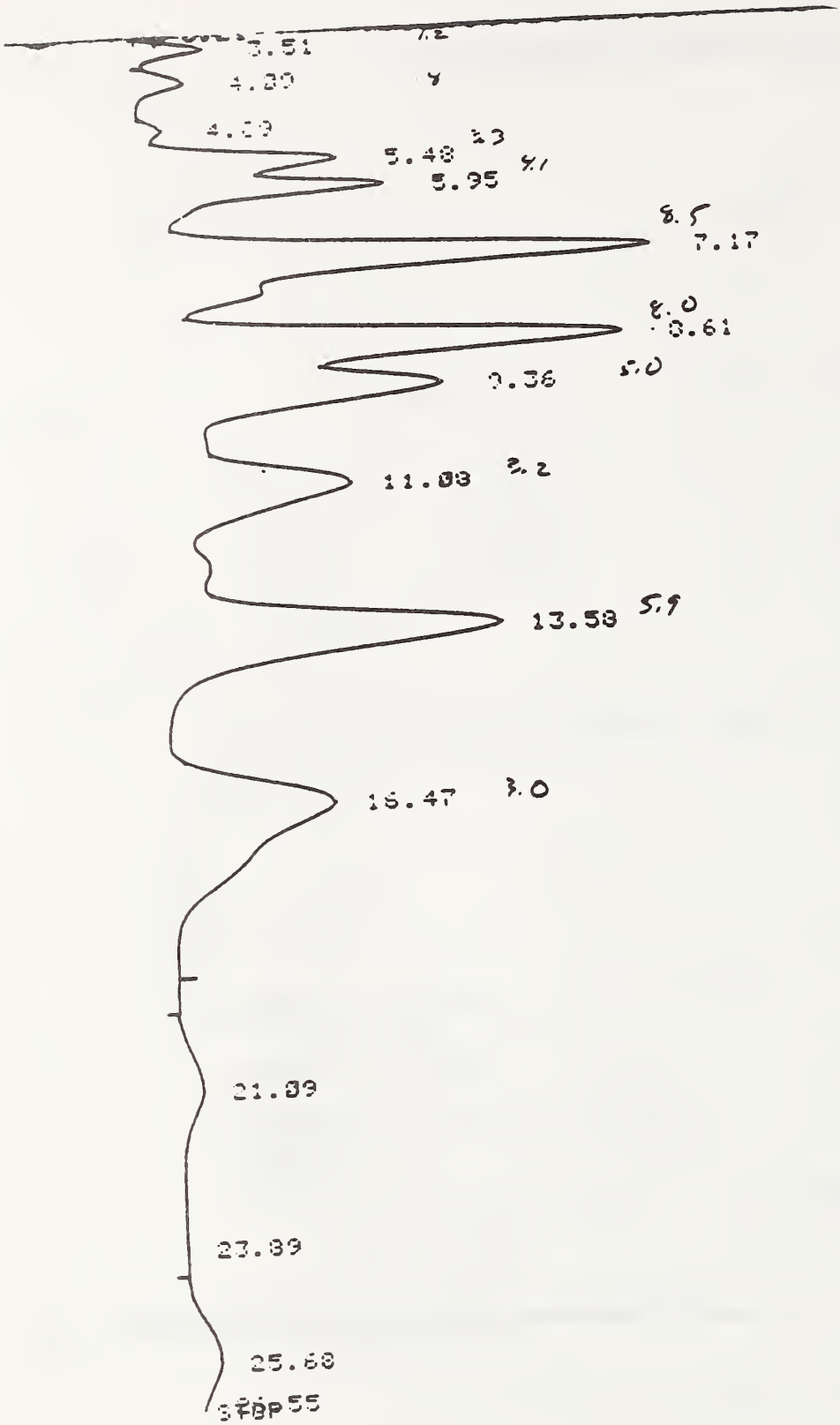


IP RUN # 81 AUG-27-79 TIME 12:10:41
ISTD

RT	EXP RT	AREA	CAL #	AMT
4.17	4.17	7750	6	0.015
7.19	7.22	125700	9	0.403
9.48	9.31	80480	11	0.200

IL FACTOR: 1.0000 E+ 0





peak [illegible]:

43.4

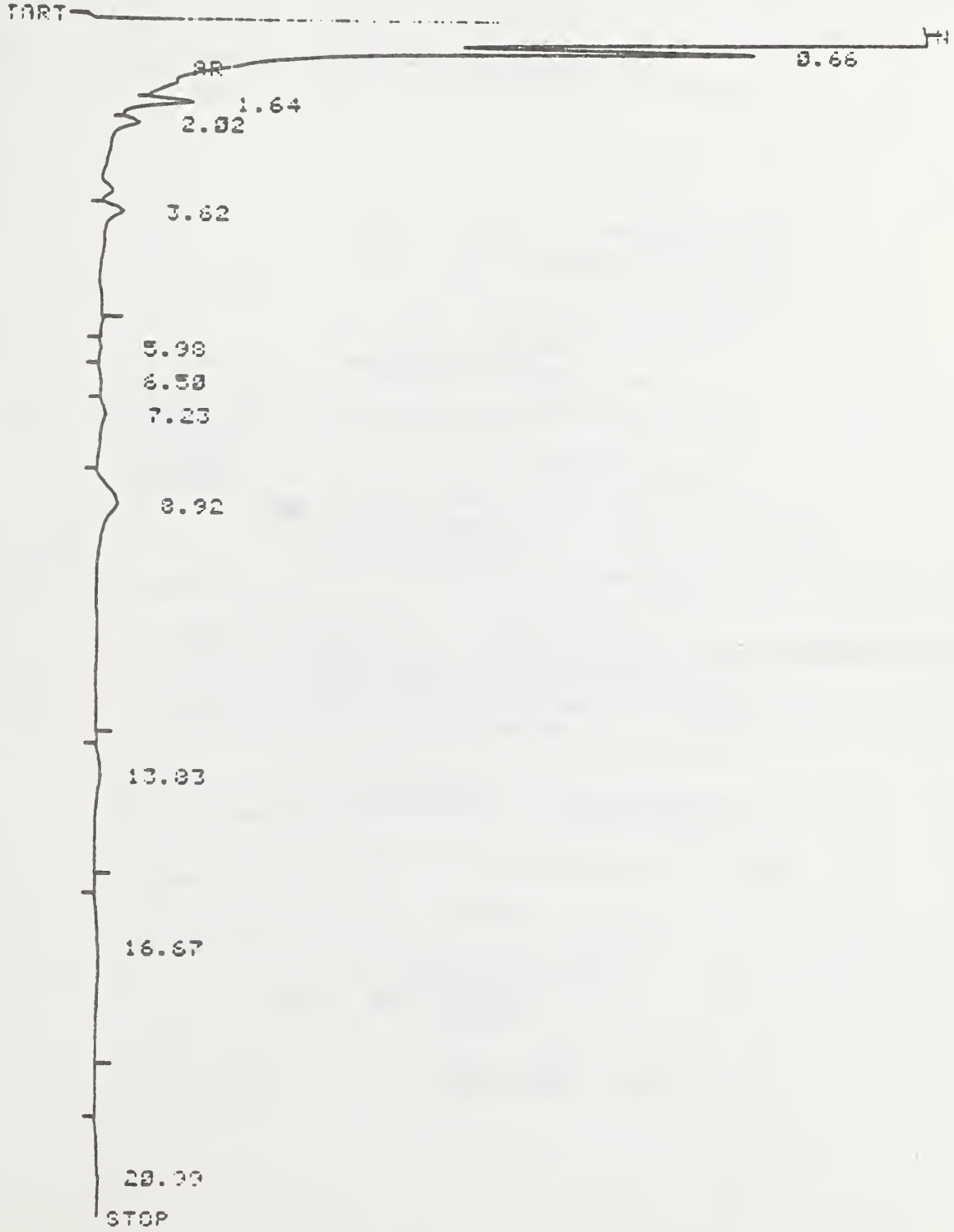
HP R' # 02 AUG/27/79 TIME 12:40:28
EOTI

RT	EXP RT	AREA	CAL #	AMT
4.30	4.17	23618	8	8.846

[illegible] # [illegible] AUG/21/79 TIME 12:40:28

	RET MT	AREA	CAL #	AMT
[illegible]	[illegible]	23610	6	0.046
[illegible]	[illegible]	182000	9	0.699
[illegible]	[illegible]	119700	11	0.379

IL FACTOR: 1.0000 E+ 0



STOP

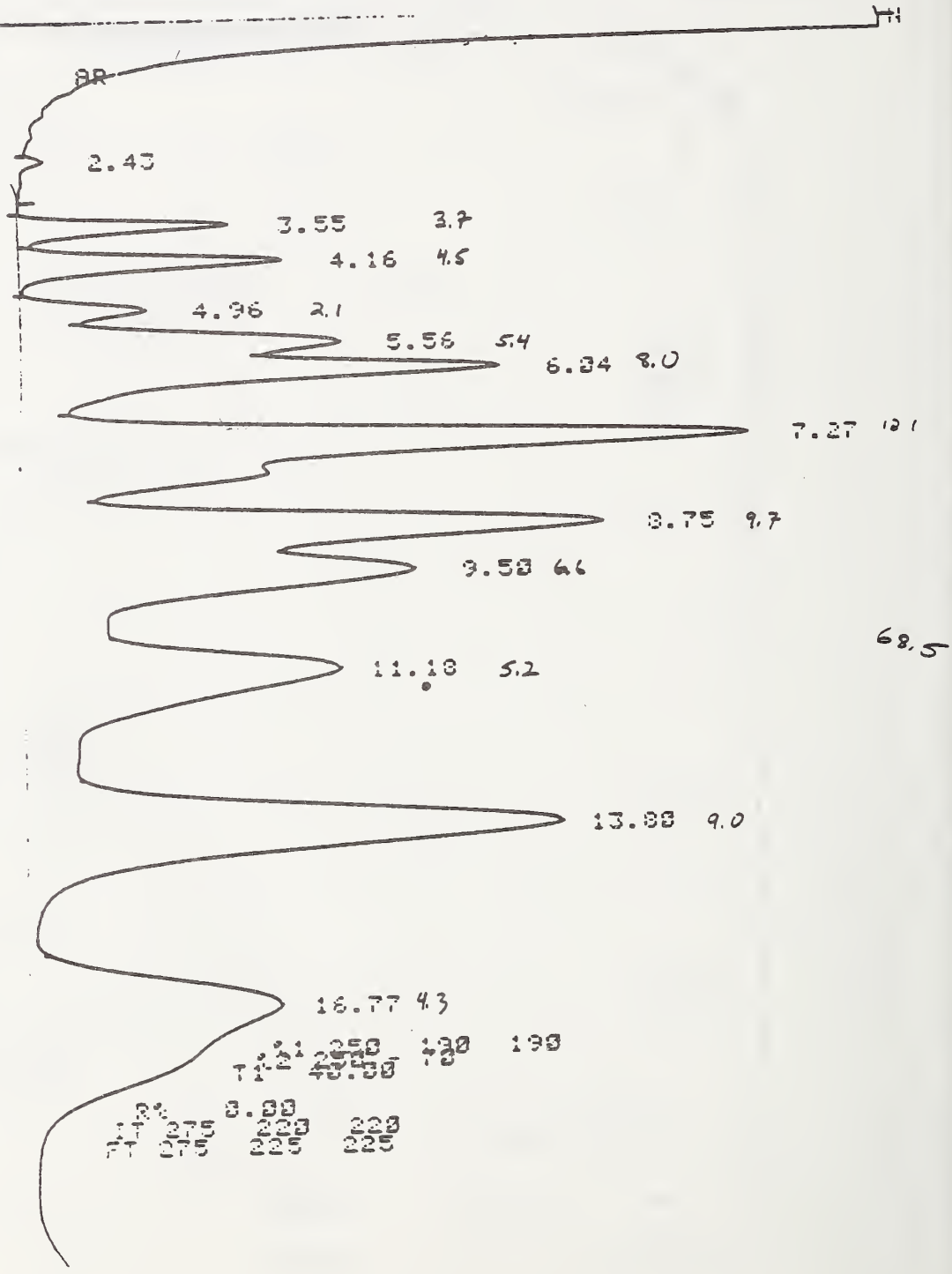
AUG/27/79 TIME 13:38:04

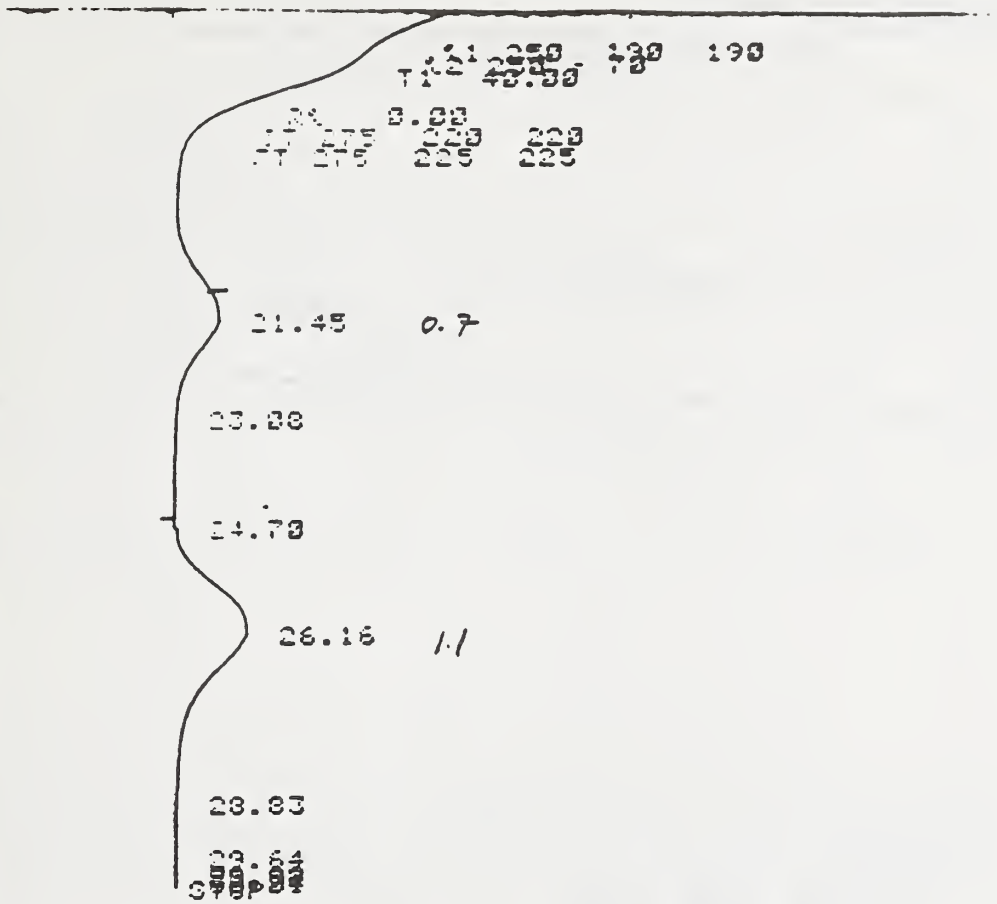
RT	EXP RT	AREA	CAL #	AMT
7.13	7.22	2235	9	0.009
13.88	14.15	1072	13	0.012

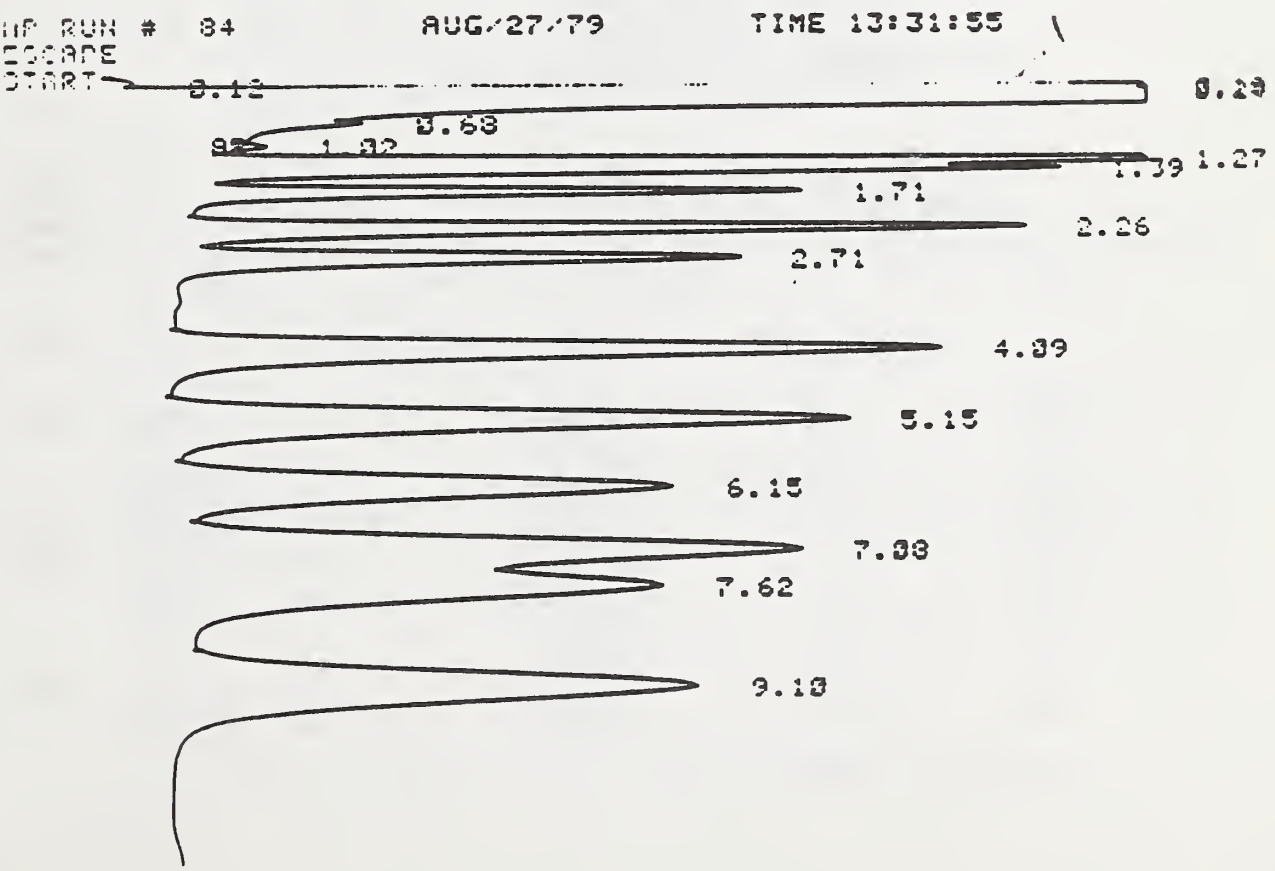
DIL FACTOR: 1.0000 E+ 0

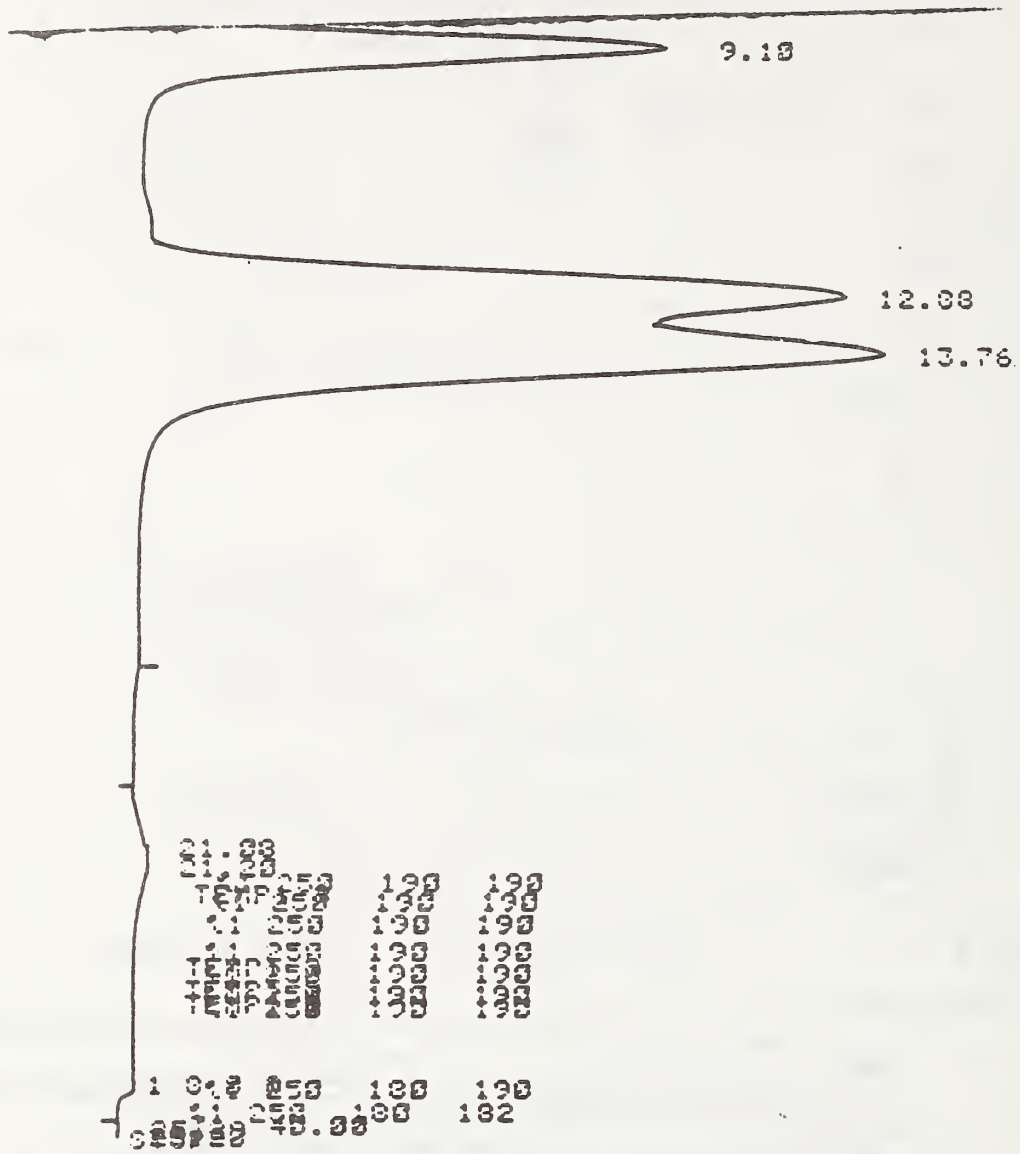
single injection

START




190
21.45
0.7
23.88
24.70
26.16
28.83


AUG/27/79
TIME 13:31:55
0.29
0.68
1.27
1.71
2.26
2.71
4.89
5.15
6.15
7.08
7.62
9.10



RUN # 05 AUG/27/79 TIME 14:02:44
TB

RT	EXP RT	AREA	CAL #	AMT
1.27	1.27	75360	2	0.126
1.39	1.39	51810	3	0.218
1.71	1.72	55730	4	0.156
2.26	2.25	83900	5	0.240
2.71	2.76	81000	(R) 1	0.250
4.09	4.20	131000	6	0.253
5.15	5.17	131000	7	0.371
6.15	6.15	111600	8	0.388
7.80	7.80	142000	9	0.545
[illegible]	[illegible]	[illegible]	10	[illegible]
9.10	9.14	100300	11	0.569
12.08	12.79	276100	12	0.658
13.76	13.89	315000	13	0.805

FACTOR: 1.0000 E+ 0

ATTACHMENT #8

7 C 7 1 [illegible]

[illegible] Egg Products
Washington, D.C. 20250

[illegible] Pocatello, Id. 83201

N/A

Bulk

Raw Whole Eggs

ORGANOLEPTIC INSPECTION						WEIGHING REPORT		
[illegible]	[illegible]	NO. OF PACKAGES [illegible]	NO. OF PACKAGES EXAMINED	ORGANOLEPTIC CONDITION: SATISFACTORY	ORGANOLEPTIC CONDITION: UNSATISFACTORY	TOTAL MARKED WEIGHT	TEST SHORTAGE	TOTAL NET WEIGHT
9-17-79	Bulk	2	—	—		4.02	—	8 oz

LABORATORY ANALYSES Pesticide Residues

Nondetected: alpha-BHC and/or HCB, beta-BHC, Lindane, p,p'-TDE, p'p'-DDE, p,p'-DDT, Dieldrin, Aldrin, Endrin, Heptachlor, H. Epoxide, PCB

Delta-BHC: Trace
O,p'-DDT: .065 PPM
Total DDE, DDT, TDE = .074 PPM

Special sample to be analyzed for Hydro-Chlorines
P-164-2 Southeastern Idaho

INSPECTOR | CHEMIST

8-1-79

David [illegible] Lab C[illegible]

Don [illegible]

LAB REPORT

(VELMA RIGGIN) ATTACHMENT #9

EST. P1313

MP from 23-1
FORM NO. 213833
Retain Tag# _____
DATE SAMPLE TAKEN 7/6/79
SPECIES Fowl

CASE NO. _____

RESULTS: Code III (PCB's) "1576" - Just

STATUS OF CASE:

Retain product if still available - NON Diff

43rd DA

Pre test - 30 birds + slaughter retain.

OWNER ~~C/S N. Bros Farms~~ Merlo [illegible]

address → Franklin Lobby, 23.237

(IF CASE IS CLOSED CALL THE VETERINARIAN OR IIC OF THE EST.)

(IF CASE IS OPEN CALL THE VETERINARIAN OR IIC OF THE EST. & VERIFY THE OWNER'S NAME & ADDRESS ALSO GIVE THEM THE LAB REPORT)

VELMA RIGGIN WILL ADVISE. . .

Notified Dr Boyer — Dr Mike N

Date 8/9/79

Spoke owner name

ATTACHMENT #10

CERTIFIED MAIL RETURN RECEIPT REQUESTED

August 16, 1979

Mr. Marlow Woodward
Sitewood Farm
Franklin, Idaho 83237

Dear Mr. Woodward: Case No. 1-373-79

The USDA's Meat and Poultry Inspection Program carries out a National Residue Monitoring Program to determine the presence of antibiotics, pesticides, herbicides, growth stimulators and heavy metals in the nation's meat and poultry supply as a part of our regular inspection program. This program is designed to detect residues and prohibit meat or poultry containing these residues from reaching the consumer in the meat or poultry portion of his diet. Presence of residues is determined by tissue analysis in a USDA chemical laboratory.

Tissue samples collected from mature chickens identified to us as originating from your premises were taken at Est. P-1313, Jolly Wholesale Poultry, Provo, Utah. These samples were found to contain residues of 15.65 parts per million of polychlorinated biphenyls (PCB) - in the fat tissue. These findings are above the regulatory action level for polychlorinated biphenyl in the edible tissues which is 3.00 parts per million. Avian tissues with residues exceeding the regulatory action level are considered unfit for food and are indicative of a biological residue violation.

In view of this residue violation, chickens marketed in the future from your premises will be subject to restrictions at the time of slaughter. Chickens originating from your premises if slaughtered will be retained and held under security pending laboratory analysis of the tissues. The birds retained will be released only after samples submitted to a laboratory approved by USDA have been found to be in compliance for chlorinated hydrocarbon residues.

Alternatively, you may present representative birds selected from the lot of chickens you next intend to market for a pretest at an inspected plant. Samples would be taken from these selected birds and submitted to a laboratory approved by USDA for analysis. These laboratory findings will determine the disposition of the rest of the chickens in that lot. This procedure would not necessitate the retention of chickens you intend to market if the pretest lot of birds are in compliance for biological residues. These restrictions will be continued until sufficient evidence has shown that chickens under your custody do not have a residue problem.

Accordingly, prior to marketing additional chickens, it is requested that you first inform our representative for your area. Our representative for your area is:

Dr. R. L. Haskell, Area Supervisor
530 Center Street, N. E., Room 405
Salem, Oregon 97301
Phone 503-399-5831
or

Dr. Walter Huber, Area Supervisor
2995 Baseline Road, Suite 105
Boulder, CO 80303
Phone 303-499-1000 X 4411

Dr. Haskell or Dr. Huber will be able to guide you in the details pursuant to the slaughter of your marketable product.

Your cooperation will be appreciated and if you need additional information, please do not hesitate to contact our representative.

Sincerely,

L. J. Roth
Regional Director

Enclosures
Memo to Dr. Haskell and Dr. Huber
Analytical Results

MTAHD/ecm

cc: Dr. R. L. Haskell, Area Supervisor, Salem, OR
Dr. Walter Huber, Area Supervisor, Boulder, CO
IIC.et Est. P-1313
Mr. J. Spaulding, FES, Science, WA., DC - SF
Hon. Wilson Kellar, Commissioner of Agriculture, Boise, Idaho
Dr. T. E. Cribar, State Director, Meat Inspection Division, Boise Idaho
Regional Food & Drug Director, FDA, Seattle, WA
EPA, San Francisco, CA (Environmental Protection Agency)
Mr. N. Okamoto, San Francisco Chemistry Lab., San Francisco, CA
Dr. L. H. Burkert, Director, Des Moines, IA

ANALYTICAL RESULTS -- [illegible] RESIDUE SURVEILLANCE PROGRAM

[illegible]	Item No.	Producer	Date Sample Collected	Establishment Number & Name	Laboratory Findings: Tissue	PPM	Compound	Compliance Status	Regulatory Action Level
[illegible]	[illegible]	Mr. Marlow Woodward Elmwood Farm Franklin, Idaho Phone: (208) 646-2250	7/6/79	Est. P-1313 Jolly Wholesale Poultry 1200 N. Riverside Drive Provo, Utah 84601	Fat	15.65	Polychlorinated Biphenyl (PCB)	Out	5.00 [illegible]

U.S. DEPARTMENT OF AGRICULTURE
[illegible] SERVICE
RESIDUE MONITORING PROGRAM

NAME AND ADDRESS OF OWNER (Including ZIP Code): TO: H. M. TRABOSH - Rm. 603 Annex Bldg.

NO

ZIP CODE

OTHER IDENTIFICATION

SPECIES: [illegible] CHICKEN

STATE OF ESTABLISHMENT: [illegible]

ESTABLISHMENT NO.: [illegible]

LOT SIZE

COLLECT FOLLOWING TISSUE: Fat

COLLECT TISSUE ON: [illegible]

SEND TISSUE TO THIS ADDRESS: [illegible]

SIGNATURE OF INSPECTOR

DATE SENT TO LABORATORY

FOR LABORATORY USE ONLY

DATE TISSUE RECEIVED: 7-20-[illegible] [illegible] Started 7-25-79

DATE TISSUE ANALYZED: 8-3-79

TISSUE TO BE ANALYZED FOR: [illegible]

DATE & TIME COLLECTED: 7-6-79 3:30 PM

[illegible] FREEZING: "

Tissue Code 1: Residue Code	Amount	Tissue Code: Residue Code	Amount	Tissue Code: Residue Code	Amount	Tissue Code: Residue Code	Amount
111	1565						

SIGNATURE OF ANALYST: M. Wong

REVIEWED BY: [illegible]

[illegible] FORM [illegible]

U KC

U.S. DEPARTMENT OF AGRICULTURE

ATTACHMENT #11

FOOD SAFETY AND QUALITY SERVICE
Meat and Poultry Inspection Program
North Central Region
U. S. Courthouse, Room 419
Des Moines, Iowa 50309

SUBJECT: PCB Residue Investigation

DATE: August 17, 1979

TO: Dr. W. F. Leese, Residue Coordinator,
RES Staff, STS

The initial investigation was a response to Dr. Pang's inquiry. An objective phase sample for PCB was positive for 4,500 mature chickens slaughtered on July 6, 1979, at Jolly Wholesale Poultry, Provo, Utah, Est. P-1313.

The product (whole birds) was shipped to Swift & Co., Clinton, Iowa, Est. P-76. The product was further processed. The boxes shipped to Swift & Co. had these marks on the boxes:

Lot #	Slaughtered	No. of Boxes
178	7/6/79	252
176	7/6/79	323
178	7/6/79	468
		1,043

There were 1,048 boxes received at Est. P-76; 236 boxes remained unopened at the establishment and remain under retention. ← These will be sampled

Of the product processed:

1740 cases (10#/case) of diced chicken are retained at Est. P-76.

60 boxes (10#/box) at: Swift First Meat Sales Unit
9930 Commerce Drive
Springdale, OH
(Cincinnati, OH)
513/874-5770
Code 9-215
UPC 23382 (Labeling Code)
Mr. Ewing notified 8/16/79
8/17/79 - Per Mr. Ewing, 65 10# boxes located at Est. 3-AJ where MPI had retained.

400 boxes (10#/box) at: (Est. 3790) Merchant Regrigeration Company
One Frozen Food Plaza
Secaucus, NJ 07094
201/867-3900
Merchandized through:

Swift & Company
1 Harmond Plaza
Secaucus, NJ 07094
201/867-0101

Code 9-215
UPC 22959
Dr. Farber notified 8/16/79 (NERO)
Product retained

Copies sent to Residue Committee

67 boxes (10#/box) at:	Consolidated Distributors c/o Inland Cold Storage 6504 Inland Drive Kansas City, KS 66110 913/375-1850	Code 9-215 UPC 22959 Mr. Campos, CS, notified 8/16/79
3 boxes (10#/box) at: (Est. 1892)	Waldman Meat Co., Inc. 809 Sampson New Castle, PA 16101 412/658-7788	Code 9-215 UPC 22959 Dr. Farber notified 8/16/79 Product retained
2 containers (25#/container) at: (Est. 3-SI)	Swift & Co. Sales Unit 2105 Hammond Drive Schaumburg, IL 60195 312/397-8088	Code 9-218 UPC 22698 Dr. Burke notified 8/16/79 Product retained

Thirty bird samples have been collected at Est. P-76 and will be submitted to the lab on August 20, 1979.

C. H. Schilmoeller, D.V.M.
Acting Director
North Central Region

cc:
Dr. N. Pang, Staff Assistant for Slaughter, WRO, Alameda, CA

Results of Laboratory Analysis of IQF Product at Plant P-76, Clinton, IA.

LABORATORY	Rendered Chicken Fat					Finished IQF Product (Pulled Chicken Meat)			
	Production Date and Date Code					Production Date and Date Code			
	7/31/79	8/3/79	8/6/79	8/7/79		7/31/79	8/3/79	8/6/79	8/7/79
	212	215	218	219		212	215	218	219
WARF Laboratory Madison, Wisconsin	5.6ppm	11.5ppm	18.9ppm	42.1ppm		.34ppm	.05ppm	1.2ppm	1.3ppm
Woodson-Tennant Laboratory Memphis, Tennessee	4.47ppm	7.57ppm	12.8ppm	25.0ppm		.29ppm	.01ppm	1.02ppm	1.2ppm

Raw Fat Samples(6 samples submitted) AS IS BASIS

	(1)	(2)	(3)	(4)	(5)	(6)
WARF Laboratory Madison, Wisconsin	NOT DETECTED			------	------	------
Woodson-Tennant Laboratory Memphis, Tennessee	1.05 ppm	.11 ppm	.12 ppm	.14 ppm	.10 ppm	.10 ppm

Information provided by James Joslyn, Food Inspector,P-9, on detail at Clinton, Iowa. 8/22/79

Samples were submitted on Monday,8/20/79,to the Government Laboratory ON THE ABOVE

The Plant wants to dump the Rendered Chicken Fat regardless of the Government Laboratory Results

Can it be denatured and go to regular inedible fat, or does it have to be buried ? Ans.- IT MUST BE BURIED

45R

USDA-APHIS MPI

LABORATORY REPORT

1. STATE CIRCUIT CODE: 14910
2. ESTABLISHMENT NO.: P1313
3. RETAIN TAG NO.: B703752 9 / B703753 6

[1] MEAT [X 2] POULT [9] OTHER (Specify) ___

ATTACHMENT #12

482608

5. DATE COLLECTED: MONTH 8 DAY 21 YEAR 79 — 10:20 AM

6. NAME AND ADDRESS OF: Mr. Marlow Woodward (Riteweed Farm) Franklin, Idaho 83237

7. IMPORT PRODUCT

a. COUNTRY NAME	CODE	b. FOREIGN EST. NO.	c. CUSTOMS ENTRY NO.	d. MP-410 NO.

8. PROGRAM PHASE (Residues): [1] OBJECTIVE [2] SELECTIVE

9. PROJECT NAME OR NUMBER: Rep Resample 1-373-79

10. RELATED SAMPLE NOS.: Samples 1-10 From 30 Samples Taken

11. ANIMAL SPECIES OR PY CLASS: Mature Chicken — CODE 63

12. APPROX. AGE: MONTHS 18 YEARS ___

13. SEX: [1] M [X 2] F [3] N

14. REQUEST FOR: PATHOLOGY: [41] HISTOPATHOLOGY [42] PARASITOLOGY

MICROBIOLOGY: [33] DIAGNOSTIC MICROBIOLOGY [32] FOOD MICROBIOLOGY [35] SPECIES IDENTIFICATION

RESIDUE: [20] ANTIBIOTIC [40] ARSENIC [60] CARBAMATE [10] CHLORINATED HYDROCARBON [50] GROWTH HORMONE

[X] OTHER (Specify) PCB Polychlorinated Biphenyls

15. SPECIMEN

Fat	Muscle	Inject. Site	Kidney	Liver	Lung	Lymph Node	Heart	Skin	Spleen
X 01	03	05	04	02	07	08	09	X 10	11

Brain	Eye or Eye Lesion	Peritoneum	Nerve	Bursa Fabricius	Adrenal Gland	Other Tissues Not Listed
12	13	14	15	16	17	06

16. RELATED INFORMATION INCLUDING IMPORTS

CODE	OTHER ITEMS	ANTE-MORTEM AND POST-MORTEM REMARKS:
		Orig. Test Sample Taken 7-6-79 by Insp D. Brinkerhoff
		Form# 213833 Date analyzed 8-3-79 by M. Wing Found
		15.45 PPM Compliance Out - Regulatory Action level 5.00 PPM
		Residue Code 111
		Phone 801-373-6052
		Please let us know results as soon as possible.
		Owner wants to slaughter more birds if possible

17. GROSS DIAGNOSIS: Suspect Residue Retest

18. INSPECTOR (Type or print): DR. R. S. Boyer — INITIALS: RSB

19. RESIDUE ONLY — IN COMPLIANCE? [1] YES [X 2] NO — CONTROL TOTAL

20. FOR LABORATORY USE ONLY

21. LABORATORY CODE: 0601

TISSUE CODE 01		TISSUE CODE	
RESIDUE CODE	AMOUNT	RESIDUE CODE	AMOUNT
111	4500		

Composite of 1-6

22. DATE REC'D.	23. CONDITION ON RECEIPT	24. ANALYSIS a. STARTED	b. COMPLETED	c. HRS.	25. SIGNATURE OF ANALYST(S)	26. REVIEWED BY:
8-23-79	acceptable	8/23/79	8/27/79		M. Wing Ronald C. Eller	HE Jr.

MP FORM 23 (6/73) PREVIOUS EDITION MAY BE USED

COPY 1 - LABORATORY - Send to Circuit

4-53R

USDA-APHIS MPI

LABORATORY REPORT

1. STATE CIRCUIT CODE: 1 | 4 | 9 | 1 | C
2. ESTABLISHMENT NO.: P 1313
3. RETAIN TAG NO.: B703753 29 / B703753 30

[1] MEAT [X 2] POULTR [6] OTHER (Specify)

ATTACHMENT #13

482437

5. DATE COLLECTED: MONTH 8 | DAY 21 | YEAR 79 — 10:20 AM

6. NAME AND ADDRESS OF: MR. Morlow Woodward (Ritenwood Farm) Franklin, Idaho 83237

7. IMPORT PRODUCT

a. COUNTRY NAME	CODE	b. FOREIGN EST. NO.	c. CUSTOMS ENTRY NO.	d. MP-410 NO.

8. PROGRAM PHASE (Residues): [1] OBJECTIVE [2] SELECTIVE

9. PROJECT NAME OR NUMBER: Rep Resample 1-373-79

10. RELATED SAMPLE NOS.: Samples 11-20 From 30 Sample Taken

11. ANIMAL SPECIES OR PY CLASS: Mature Chicken — CODE 63

12. APPROX. AGE: MONTHS 18 / YEARS

13. SEX: [1] M [X 2] F [3] N

14. REQUEST FOR: PATHOLOGY: [41] HISTOPATHOLOGY [42] PARASITOLOGY

MICROBIOLOGY: [33] DIAGNOSTIC MICROBIOLOGY [32] FOOD MICROBIOLOGY [35] SPECIES IDENTIFICATION

RESIDUE: [20] ANTIBIOTIC [40] ARSENIC [60] CARBAMATE [10] CHLORINATED HYDROCARBON [50] GROWTH HORMONE

[X] OTHER (Specify) PCB Polychlorinated Biphenyls

15. SPECIMEN

Fat	Muscle	Inject. Site	Kidney	Liver	Lung	Lymph Node	Heart	Skin	Spleen
X 01	03	05	04	02	07	08	09	X 10	11

Brain	Eye or Eye Lesion	Peritoneum	Nerve	Bursa Fabricius	Adrenal Gland	Other Tissues Not Listed
12	13	14	15	16	17	06

16. RELATED INFORMATION INCLUDING IMPORTS

CODE	OTHER ITEMS	ANTE-MORTEM AND POST-MORTEM REMARKS:
		Orig. Test sample taken 7-6-79 by Insp D. Brinkerhoff
		Form # 213833 date analyzed 8-3-79 by M. Wong found
		15.65 ppm Compliance Ent - Regulatory Action level 500 ppb
R		Residue Code 111
		Phone 801-373-6052
		Please let us know results as soon as possible.
		Owner wants to slaughter more birds if possible.

17. GROSS DIAGNOSIS: Suspect Residue

18. INSPECTOR (Type or print): DR. R. S. Boyer — INITIALS: RSB

19. RESIDUE ONLY — IN COMPLIANCE? [1] YES [X 2] NO — CONTROL TOTAL

20. FOR LABORATORY USE ONLY

21. LABORATORY CODE: 0 | G | 0 | 1

TISSUE CODE 01		TISSUE CODE	
RESIDUE CODE	AMOUNT	RESIDUE CODE	AMOUNT
111	6700		
111	5400		

→ Composite of 7-12

→ 13-18

22. DATE REC'D.: 8-23-79

23. CONDITION ON RECEIPT: acceptable

24. ANALYSIS: a. STARTED 8/23/79 | b. COMPLETED 8/27/79 | c. HRS.

25. SIGNATURE OF ANALYST(S): M Wong, Ronald D. Clarke

26. REVIEWED BY:

MP FORM 23 (6/73) PREVIOUS EDITION MAY BE USED

COPY 1 - LABORATORY - Send to Circuit

LAB ACC. # / DATE RECD: 1,03R 8-23-79

ATTACHMENT #14

SERIAL NO: 271077

1. PROJECT NAME OR CASE NO.: Rep. Resample 1-373-79 | CASE NO.:
2. RELATED SERIAL NOS. (Use item 15 if needed): Samples 21-30 From 30 samples Taken
3. RETAIN TAG NO.: B7037529 B7037530

4. REASON FOR SAMPLING: ☐ 1 INSPECTOR INITIATED ☒ 2 PROGRAM INITIATED

5. NAME AND ADDRESS OF PRODUCER, HERD OR FLOCK OWNER: Mr. Marlow Woodward (Riverwood Farm) Franklin, Idaho — ZIP CODE: 83237

6. STATE CIR. CUIT CODE: 14910

7. ESTABLISHMENT NO: P1313

8. PRODUCT OR SPECIES: Mature Chickens — CODE: 63

9. APPROX. AGE: MOS. 18 YRS.

10. SEX: ☐ 1 M ☒ 2 F ☐ 3 N

11. DATES: A. COLLECTED 10:20 AM MO. 8 DAY 21 YR. 79 — B. MAILED MO. 8 DAY 22 YR. 79

12. IMPORT PRODUCT

A. COUNTRY NAME	CODE	B. FOREIGN EST. NO.	C. CUSTOMS ENTRY NO.	D. MP FORM 410 NO.

13. REQUEST FOR: ☐ PATHOLOGY ☐ DIAGNOSTIC MICROBIOLOGY ☐ FOOD MICROBIOLOGY ☐ FOOD POISONING ☐ SPECIES IDENTIFICATION

RESIDUE (Enter residue code if request is known - See reverse): (PCB) Poly Chlorinated Bi Phenyls — CODE: 111

14. SPECIMEN: ☒ 01 FAT & SKIN ☐ 02 LIVER ☐ 03 MUSCLE ☐ 06 OTHER (Specify) ☐ 04 KIDNEY ☐ 05 INJECT SITE

15. RELATED INFORMATION (Including Imports, Ante-Mortem and Post-Mortem remarks):
Orig. Test sample Taken 7-6-79 by Insp. D. Brinkhoff Form #213833 date analyzed 8-3-79 by M. Wong found 15.65 ppm - Compliance Out - Regulatory Action Level 5 ppm. Residue Code 111
Please let us know results as soon as possible, Owner wants to slaughter more birds is possible.

16. NAME OF INSPECTOR (Type or print): DR. R. S. Boyer — PHONE NO. (Include Area Code): 8013736052

17. RESIDUE ONLY—IN COMPLIANCE: ☐ 1 YES ☒ 2 NO

18. FOR LABORATORY USE ONLY

Residue Code	Amount	Tissue	
111	3600	01	Composite of 19-24
111	4700	01	25-30

19. DIAGNOSIS

20. LABORATORY CODE: 0601

21. CONDITION ON RECEIPT: acceptable

22. ANALYSIS DATES: A. STARTED (MO., DAY, YR.) 08 23 79 — B. COMPLETED (MO., DAY, YR.) 08 27 79

23. NO. T | 24. NO. S

25. SIGNATURE OF ANALYST(S): M. Wong, Ronald Erdner, INITIALS

26. REVIEWED BY: M. C.

MP FORM 23 NOV. 1977 PREVIOUS EDITIONS OBSOLETE

COPY 1 - LABORATORY - Send to Inspector (Inspector: Insert name and address on reverse of copy 1, or include a self-addressed envelope.)

ATTACHMENT #15

Telecopied to Dr. Prucha 9/19/79
this correspondence: 8/31 back to 7/6/79
NP: mk

August 31, 1979

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Marlow Woodword
Ritewood Farm
Franklin, Idaho 83237

Dear Mr. Woodword: Case No. 1-373-79

We are adding the enclosed information to our file on this case. As a result, the enclosed sampling plan will be utilized on future lots sent to slaughter. Retention of (birds) pending test results will be continued until the problem is resolved.

We suggest that you consult with your veterinarian, county agent, state department of agriculture, university or FDA, as appropriate to help with this serious problem.

If you should need further assistance, please contact our representative in your area. Their names and addresses are:

Dr. Walter Huber, Area Supervisor
2995 Baseline Road - Suite 105
Boulder, CO 80303
Phone 303-499-1000 X 4411

or

Dr. R. L. Haskell, Area Supervisor
530 Center Street, N.E. - Room 405
Salem, Or 97301
Phone 503-399-5831

In addition, please continue to provide advance notification of time and place of slaughter.

Sincerely,

L. J. Rafoth
Regional Director

Enclosures
Memo to Dr. Huber
Memo to Dr. Haskell
Analytical Results

cc: Dr. Walter Huber, Area Supervisor, Boulder, CO
Dr. R.L. Haskell, Area Supervisor, Salem, OR
IIC at Est. P-1313
Dr. J. Spaulding, RES, Science, WA., DC-SP
Hon. Wilson, Kellogg, Commissioner of Agricultare
Dr. V. E. Coiner, State Director, Meat Inspection
EPA, San Francisco, CA (Environmental Protection Agency).
Mr. M. Okamoto, San Francisco Chemistry Lab.
Dr. L. H. Burkett, Director, Des Moines, IA
Dr. A. P. Schneider, Idaho Dept. of Agriculture

MN

ANALYTICAL RESULTS - MPI RESIDUE SURVEILLANCE PROGRAM

: No.	Form No.	Producer	Date Sample Collected	Establishment Number & Name		Laboratory Findings Tissue	PPM	Compound	Compliance Status	Regulatory Action Level
3-79	271077	Marlow Woodword	8/21/79	Est. P-1313	*1.	Fat	45.00	Polychlorinated	Out	5.00 ppm
re		Ritewood Farm		Jolly Wholesale	2.	Fat	67.00	Biphenyl (PCB)		
kens		Franklin, Idaho		Poultry	3.	Fat	54.00			
		Phone:		1700 N. Riverdale	4.	Fat	36.00			
		(208) 646-2250		Dr.	5.	Fat	47.00			
				Provo, Utah 84601						
	482437	Same	8/21/79	"						
	482608	"	8/21/79	"						

* 1.	Composite of group of six (6) birds	1 thru 6
2.	" " " " " " "	7 thru 12
3.	" " " " " " "	13 thru 18
4.	" " " " " " "	19 thru 24
5.	" " " " " " "	25 thru 30

U.S. DEPARTMENT OF AGRICULTURE

Memorandum

FOOD SAFETY AND QUALITY SERVICE

Poultry and Dairy Quality Division

TO: Regional Directors

DATE: September 25, 19

ATTACHMENT #16

FROM: D. A. Niebuhr, Chief
Poultry Grading Branch

SUBJECT: Adulterated Products

You are aware of our responsibilities on adulterated eggs and egg products, i.e., product contaminated by pesticides, such as DDT, and hydrocarbons, such as, PBB's, PCB's, etc. All supervisors must report any contacts regarding this subject received from industry, federal agencies, cooperating state agencies, to this office immediately. Our memorandum of understanding with FDA also requires that we contact their local office and set up a method of coordinating information back and forth between agencies.

We must take prompt and positive action when contacted. Please discuss this memo with all field supervisors and advise us when this has been accomplished.

Donald A. Niebuhr, Chief
Poultry Grading Branch

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND QUALITY SERVICE

Memorandum

ATTACHMENT #17

TO : Deputy Administrators DATE: OCT 2 9 1979

FROM : Donald L. Houston
Administrator

SUBJECT: Memoranda of Understanding with FDA and EPA with Regard to Drug, Pesticide, and Industrial Chemical Residues in Animal Feeds and in Meat, Poultry, and Egg and Dairy Products

This confirms and provides you with a record of a decision reached on October 3, 1979.

On April 4, 1975, a memorandum of understanding between APHIS and FDA went into effect whereby each agency undertook several responsibilities in order to coordinate the handling of residue violations in feeds and foods. By reorganization, FSQS is now a party to that memorandum of understanding.

On August 17, 1977, a memorandum of understanding went into effect between EPA and FSQS with a similar intention--to coordinate the handling of residue violations.

Both agreements recite the USDA undertaking in terms chiefly of meat and poultry. However, FDA and EPA both undertake to agree to report violations in milk and eggs as well as meat and poultry. In order to control residues to the fullest extent possible, it is now FSQS policy that Commodity Services, as a unit of FSQS with an interest in residues in milk and egg products, be a party to the memoranda of understanding. As such, Commodity Services will assume the commitments established for FSQS in the agreements, as such commitments relate to milk and egg products.

UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Quality Service
Meat and Poultry Inspection Program
Washington, DC 20250

MPI BULLETIN 79-99
9/26/79

ATTACHMENT #18

ACTION BY: Inspectors in Charge at Slaughter Plants

INFORMATION FOR: Regional Directors, Area and Circuit Supervisory Personnel and MPI Laboratories

Mailing of Residue Samples

We have recently become aware of a problem involving the prompt submittal of residue samples to MPI Laboratories.

In accordance with MPI Bulletin 77-114, item 7, residue samples must be sent to the laboratory on the next workday following sampling. The samples must, however, be thoroughly frozen. FSQS laboratories receive samples 7 days per week, therefore, all work days, including Friday are suitable for mailing samples.

Holding samples beyond 24 hours or the time necessary for proper freezing at the plant results in delayed reporting time for test results. This problem is significant, especially when violations occur and when product recall and interaction with FDA, EPA, State and other organizations is delayed.

M A. Nelson

Acting Deputy Administrator
Meat and Poultry Inspection Program

NOTE: To be reproduced and distributed by RC and regional offices according to indicated codes.

DISTRIBUTION:	CATEGORY:	REGS:	OPI:
M-90 by RC M-04 by Science M-09, M-12, M-25, M-26 by RO	K-Laboratory	MANUAL:	DA-MPI

Washington, DC 20250

Regional Directors

SEP 26 1979

ATTACHMENT #19

P. J. Prucha, Acting Assistant Deputy
Administrator, Field Operations

Environmental Contaminants

A recent accident involving the industrial chemical polychlorinated biphenyl (PCB) has resulted in the use of a contaminated animal feed component and the resulting possible widespread contamination of human food supplies.

For the future, it is important for us to take immediate action upon notification of violative laboratory results for PCB's or other environmental contaminants as they become known to us. This action should include:

1. Immediate efforts to traceback the violative sample to the farm of origin, if not already known.

2. Notification by phone to FDA and EPA regional offices that a violative level has been reported and that further information will be forwarded by phone when received.

3. Followup letters to both the FDA and EPA regional offices giving full traceback results and other complete information when it is compiled.

PSQS:MPI:FO:PJPrucha:af:ext.73697:9/26/79

ATTACHMENT #20

UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Quality Service
Meat and Poultry Inspection Program
Washington, DC 20250

MPI BULLETIN 79-109
10/29/79

ACTION BY: Inspectors in Charge

INFORMATION FOR: Regional Directors, Area and Circuit Supervisory Personnel, Plant Management, and Interested Parties

Sources of PCB Contamination

Recent events have demonstrated the severe disruption, hardship, and expense that polychlorinated biphenyl (PCB) contamination can cause. It appears that one accident involving one transformer may be responsible for millions of dollars in product loss and in cost of controlling the hazard.

FSQS is considering measures to reduce or eliminate the chances of future contaminating occurrences. Inspectors in charge are to assist in this effort by:

(1) Alerting plant management to the potential hazard of PCB usage in their plants. The current PCB problem appears to have had its origin in the leakage of the chemical from a spare transformer in an official establishment.

(2) Requesting plant officials to inventory equipment which may contain PCB's. PCB's are frequently used as heat exchange media and, therefore, might be found in such items as capacitors, transformers, heat exchangers, and hydraulic systems. Inspectors in charge should request a list of such equipment including number of pieces, location, name of manufacturer, and model number. In the case of capacitors, motors known to have dry capacitors and fluorescent fixtures need not be included.

Because of the stable nature of PCB's even after a supposed disposal, plant officials should not undertake disposal of PCB's without guidance from the Washington office. Inquiries should be directed to:

DISTRIBUTION:	CATEGORY:	REGS:	CPI:
		MANUAL:	DA/TS

MPI BULLETIN 79-109

Dr. W. O. Caplinger
Acting Director
Facilities, Equipment, and
Sanitation Division
Technical Services, MPI, FSQS
Washington, DC 20250

Area Code (202) 447-5627

Inspectors in charge should submit the inventory to Dr. Caplinger at the above address by November 23, 1979.

M. A. Nelson, for

Deputy Administrator
Meat and Poultry Inspection Program

ATTACHMENT #21

Impact Statement: Title III - Residue Prevention

1. Title:

Residue Prevention Act - Amendments to the Federal Meat Inspection Act and the Poultry Products Inspection Act.

2. Nature of Proposed Action:

The proposed bill would amend Section 1, 10 and 202(a) of the Federal Meat Inspection Act and Sections 4, 9(a) and 11(b) of the Poultry Products Inspection Act, and would add new Sections 25, 26, and 8a, respectively. These legislative amendments would: (1) permit quarantine of all food animals on a premise of origin identified as a source of animals containing drug and chemical residues determined violative by appropriate Federal agencies; (2) require identification of all animals presented for slaughter along with appropriate records to enable tracing to premises of origin; and (3) permit Federal operation of the authorized program without prejudice to States until "at least equal to" authority is determined to exist and be exercised in a State or Territory.

3. Purpose and Need For Action:

In her statement before the Subcommittee on Oversight and Investigations, of the Interstate and Foreign Commerce Committee, Assistant Secretary Carol Foreman articulated the problem:

> ... the safety of the chemicals in our food supply is a matter of growing concern to the American public...
>
> The great productivity of American agriculture today is based upon the use of chemicals to combat plant and animal pests and diseases. The discovery following World War II that pesticides, like DDT, could be used to destroy certain insect pests of plants kindled the interest of agriculturalists in attacking other pest and disease problems with chemicals. Scientists and technologists responded to the challenge with ingenuity, and developed a whole host of chemical "solutions" to farm production problems. The result is that today we are dependent of pesticides, drugs and other chemicals to maintain current levels of production.
>
> The difficulty, of course, is that until quite recently few people recognized that there might be some unintended and unfortunate consequences of an agricultural system becoming more and more dependent on chemicals....

Evidence has accumulated that health hazards have evolved from the continuous use of chemicals once considered safe. Three classes of public health hazards are associated with repeated exposure to low levels of certain residues: (1) cancer health hazards; (2) antibacterial resistance health hazards; and (3) allergic reactions health hazards.

A 1978 USDA ESCS study, "The Economic Effects of a Prohibition on the Use of Selected Animal Drugs," provides the following information about cancer-related hazards:

> There is a generally accepted belief that diet is an explanatory factor in causing cancer at some body sites. The overnutrition problem, characterized by a high intake of meats, dairy products, fats and refined flour and sugar, may be related to as many as half of all cancers in women and one third in men, according to Eckholm and Record.
>
> Besides the foods themselves, there is also a belief that food additives or contaminants may cause cancer in humans. Some food dyes, artificial sweeteners, food preservatives, and animal drugs are either proved or suspected carcinogens. Exactly how the additives and foods interact along with mode of cooking to cause cancer is not known. And the fact that there is a long delay between the stimulus that causes cancer and the appearance of the disease adds further difficulty in determining the relationship.[2]
>
> Long-term, low-level exposure to residues, or metabolites of these drugs, via human consumption of meat, milk and eggs of treated animals, may pose a public health hazard. However, both the amount of actual consumption of these suspected carcinogenic agents by humans, and consequently, the magnitude of the health risk remain unknown to date.[3]

The second important public health considerations concerns the impact of drug residues on resistance patterns. An FDA Consumer Memo provides the information on "Antibiotics and the Foods You Eat."

> FDA has been actively concerned for several years with the use of antibiotics in animal feeds. In 1970, the Commissioner appointed a Task Force to study the effectiveness of such use and whether it is safe for animals and humans. In 1972, the Task Force reported that:
>
> The use of some antibiotics, especially in long term, low-level (subtherapeutic) amounts, causes an increase of antibiotic-resistant intestinal bacterial in animals.

> Food producing animals are a major reservoir of certain bacteria (e.g., Salmonella) that are harmful to humans. The use of certain antibiotics increases the prevalence of resistant disease-causing bacteria that can be transmitted to the intestines of humans.
>
> Human illness and death have been reported that were due to antibiotic resistant bacteria that came from animals.[4]

FDA has been particularly concerned about the development of antibiotic resistant Salmonella pathogens from feeding of antibiotics. Estimates of the cases of Salmonellosis occurring annually are between 2 and 2.5 million, many of them unreported because of their mildness and/or their similarity to flu.. In a 1978 economic impact assessment of proposed rules on penicillin/ tetracycline containing pre-mixes, there is an estimate of losses attributable to antibiotic resistance: 15 percent of the cases are associated with meat from livestock and poultry fed these antibiotics.

The third public health hazard associated with residue consumption is drug-sensitivity; drug residues in contaminated meat can produce direct toxic effects, ranging from mild sensitizing responses to rashes to fatal shock. In discussing this problem in 1975 one expert noted:

> First, with regard to the sensitizing responses of antimicrobial agents, there are no data available from which an accurate estimate of the incidence of drug-sensitive people in the total population could be determined. Most of the information comes from surveys within a hospital environment or district by a hospital. From this type of data, an estimate has been made that approximately 7.2 percent of the population are hypersensitive to penicillin. As little as 10 units per orum have produced mild reactions in man. Streptomycin sensitizes readily and 2.3 percent of the people having been exposed to it have developed allergies, whereas streptomycin contact dermatitis has been reported in 72 percent of the workers in a streptomycin factory. Neo-mycin has cross-sensitization properties with streptomycin and it has been reported that 5.7 percent of a population were sensitive to this drug. Hypersensitivity to bacitracin has been reported to be between 0.3 percent and 7.8 percent of a defined population.
>
> It is not essential that the percentages of hypersensitive people be accurate. It is sufficient to know that a sizable segment of the population can react adversely to antimicrobial drugs. The unanswered question, and the one that is unlikely to be resolved in the near future, involves the relationship between the dose and hypersensitivity reactions. If such data were available, more rational decisions could be made regarding

> the role drug residues might play in this syndrome. Of course there is always the possibility that there is no dose-response relationship in which case exposure rates would become more critical.[6]

While the details of the public health hazards associated with consumption of meat and poultry contaminated with residues are not known with precision, the dimensions of the problem can be termed significant; implications of what is now known are serious enough for increased consumer concern; and recent developments suggest that improved toxicology may reveal more damaging rather than comforting data.

Three Federal agencies share responsibility for protecting consumers from illegal and potentially harmful residues of animal drugs, pesticides, and environmental contaminants in raw meat and poultry: the Food and Drug Administration, the Environmental Protection Agency and the Department of Agriculture. A recent GAO report on the subject describes the responsibilities of each:

> The Food and Drug Administration is responsible under the Federal Food, Drug, and Cosmetic Act for (1) insuring the safety of drugs given to food-producing animals, (2) setting a limit, or tolerance, on the amount of an animal drug or environmental contaminant allowable in food, and (3) preventing the marketing of raw meat and poultry containing residues above tolerance levels....
>
> The Environmental Protection Agency is responsible for (1) insuring the safety and effectiveness of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, (2) setting tolerances for pesticide residues in food under the Federal Food, Drug, and Cosmetic Act, and (3) regulating under the Toxic Substances Control Act the introduction into the environment on most chemical substances not regulated as drugs, pesticides, or food additives....
>
> Agriculture is responsible under the Federal Meat Inspection Act and the Poultry Products Inspection Act for preventing the marketing of adulterated raw meat and poultry, including those containing residues in excess of tolerances.[7]

The report goes on to brand the combined Federal effort as relatively ineffective.

USDA carries out its responsibilities through a National Residue Program, made up of two-phased sampling. The first is the monitoring phase which is used to establish incidence and trends for some 60 residues through testing a random selection of tissues from animals presented for slaughter. In 1978, approximately 20,000

tests were carried out in the monitoring phase. The second phase, known as surveillance, goes into effect whenever a residue problem is suspected in an animal or a group of animals. Animals are sampled in this phase because they belong to a group where violative residues have been found or because there are other indications that the animal may contain violative residues (such as the presence of an injection site). When a violative animal is identified, an effort is made to determine the premises or location where the violation occurred. If there are other animals at the location that are likely to also be contaminated, then followup action is attempted.

Prior to the GAO report, USDA was aware of weaknesses in the program; Foreman described them:

> There are also serious weaknesses in our program. Obviously, inadequate technology is one. Second, our resources are finite. We do not test as many animals for as many different types of residues as we think we should. Third, there are no test methods suitable for regulatory purposes for testing for some chemical residues. Fourth, when we find residues in animals during the regular monitoring program, the meat from those animals has already reached the market and been consumed. The reason for this is that we have no justification for holding an animal pending tests for residues until we have some evidence that residues, in fact, are present. Some livestock producers have learned to avoid hold and test restrictions by selling their animals in distant markets, or by marketing through middlemen. Since we have no authority to quarantine, and there is no national animal identification system there is little we can do to prevent this.[8]

The legislative amendments proposed here address specific gaps in the USDA authority. A system of animal identification will enable the Department to trace to its premises of origin any carcass with violative levels of residues. Currently, about 80% of mature cattle and 60% of the hogs produced can be traced to premises of origin. Quarantine authority will provide a more effective tool for dealing with owner/producers of violative carcasses. Currently, almost half of the identifiable violators are not complying with voluntary "hold and test" provisions.

4. Groups Impacted:

The proposed legislation would have impacts on four distinct groups:

(a) Producers and other operators of premises of origin in the production and marketing chain where contamination of animals by chemicals or drugs occurred. Such premises would include those with animals suspected or known to have received treatments having inadequate withdrawal time, or feed from a common

source suspected or known to have been accidentally contaminated with chemicals or drugs through industrial or agricultural use. Premises subject to quarantine could include: (1) farms, 2) stockyards, (3) salebarns, (4) buying and holding stations, and (5) other points in the marketing chain where livestock can be fed, treated or contaminated with drugs or chemicals.

(b) Official slaughter establishments who would be responsible for seeing that all animals slaughtered are properly identified. The identification requirement would also affect the other intermediate points in the marketing chain as well as producers, since slaughter plants would accept only animals that were properly identified and accompanied by the records necessary to accomplish identification. One of the primary impacts on official establishments, as well as prior points in the marketing chain, would be the need for some additional recordkeeping.

(c) States, particularly the 32 that now maintain "at least equal to" inspection programs. Since the quarantine authority can be enforced by USDA at premises of origin, these States will not be unnecessarily affected unless they choose to enact similar state legislation. State inspection programs will be affected indirectly by requirements for identifying violative carcasses found at State-inspected slaughter plants. If a state discovers a residue violation through its sampling program, it will be required to notify USDA so follow-up quarantine action can be taken.

(d) Consumers, to the extent that they purchase and consume meat and poultry products. It is anticipated that consumers would be favorably affected by a reduction in the amounts of residues in food consumed. Consumers may be adversely affected to the extent that they experience higher costs or interruptions in supply due to actions affecting producers.

5. Options Considered:

(a) No program - discontinue current USDA efforts.

There is some thinking that the weaknesses in the existing program are such that its impacts are imperceptible. Disbanding current USDA efforts would free up funds, laboratory facilities and personnel for work on other, less complex problems.

(b) Status quo - leave the meat and poultry inspection statues in their present form, and operate existing program as planned for FY 80.

In 1978, 20,982 meat and poultry tissue samples were collected through the National Residue Monitoring Program. Displayed below are selected sample sizes and violation rates for certain species/ residue combinations:

Selected Yearly Data for 1978 - Monitoring

Class	Cattle	Swine	Chickens	Total Samples	Total Violations
100 Chlorinated-hydrocarbons	967/10	411/2	367/0	2432	13
200 Antibiotics	1796/46	1399/76	470/8	6050	283
800 Sulfonamides	243/2	6678/648	119/1	7978	676
Total Samples/ Total Violations	5199/67	9412/726	1545/9	20892	981

Current plans call for a FY 1980 National Residue Program effort at $11.8 million, approximately twice the size of the current effort. At this level, it is anticipated that 40,000 monitoring samples will be analyzed, twice the number sampled in FY 1979. Certain other activities will be initiated to upgrade the program. The STOP program (swab-test-on-premises)--a new screening program to detect antibiotic residues in animal kidneys in a matter of hours, before the carcass would normally leave the slaughterhouse--will be in its first full year of operation, providing a substantial increase in the number of carcasses which can be rapidly tested for violative levels of antibiotic residues. Efforts will continue to develop additional rapid test techinques. No change is anticipated in the estimated 60 - 80% rate of identification or on the approximately 50% rate of voluntary cooperation with hold and test provisions.

(c) Quarantine authority alone - amend FMIA and PPIA to provide quarantine authority, but not an identification requirement.

The Department has direct experience with infectious animal disease quarantine programs and familiarity with state level residue quarantine operations; experience in the State of Virginia with a residue quarantine program provides a possible model. That program operates in the following manner:

When a producer of carcasses with violative levels of residues has been identified he is visited by a two-person team from the State, a representative of the medicated feeds section and a representative from the animal health division. The former has concurrent authority to investigate the matter in behalf of FDA; the latter is

usually a veterinarian or person trained in animal husbandry. State experience indicates that the initial visit, including travel to and from sites, requires 1 day on the average and costs approximately $500.

The purposes of the initial visit are several: (1) place the premise under quarantine; (2) develop the case history of the problem by reviewing with the producer practices and conditions which contributed to it, and collecting samples as needed; (3) provide educational and technical assistance designed to enable the producer to identify and correct the problem and prevent recurrence.

We would expect to model our education/technical assistance program after the sulfa control program set up by the USDA and FDA, in cooperation with all segments of the industry. The sulfa program consists of three phases:

--On-farm survey: an initial survey to better identify the most common sources of sulfa residues. The results of the survey are used to help producers whose hogs have been found to have above-tolerance residues in solving their individual problem.

--Expanded information/education campaign: The responsible USDA agencies, FDA, State Extension services, state departments of agriculture, producers' organizations, feed manufacturers, drug firms, veterinarians, marketing agencies, and other concerned groups, work together to make sure that everyone connected with pork production knows what to do to help eliminate above-tolerance residues.

--Stepped up research: A lot of "unknowns" still exist on the causes of residues, and what must be done to avoid residues. So, research provides the basis for finding the needed answers. These studies are conducted through USDA and cooperating organizations and State research facilities.

Under the Virginia program, when a producer at a quarantined premisis plans to send animals to slaughter, he notifies the State and requests a release; if granted, he sends "representative" animals ahead to the slaughterhouse for testing. If pretest results show a return to compliance, a second visit is made to review the situation with the producer; if adequate improvements have been made, the quarantine is relaxed to a conditional status. The producer is free to move animals providing he notifies the State when and where the animals will be slaughtered. At least one sample will be tested from these animals. If this test is acceptable, the quarantine is lifted; if not, the quarantine is reestablished.

Review of the essential features of the Virginia program with State officials in larger jurisdictions confirm that this would be a viable operating model. In a Federal effort, Regional offices would perform functions carried out by the State unless States choose to operate their own programs. Travel costs would be necessarily higher because of greater distances. Visits to premises to issue quarantines, conduct on-farm assessments and provide educational information to producers would be utilized; provisions could be made for multiple follow-up visits for difficult problems. Site visit teams could be staffed via cooperative interagency agreements with APHIS and interested States to provide an additional field workforce on a reimbursable basis. It is possible that the existing Memorandum of Understanding with FDA could be expanded to include provision for joint investigative authority, as is the case at the State level.

(d) Quarantine and identification - amend the FMIA and PPIA as proposed to provide quarantine authority and an animal identification requirement. Features of a viable program under the proposed option would include those described above and associated with the quarantine authority. Additionally, the following elements would characterize the animal identification requirement.

The nature of the animal identification system and type of devices to be used would be left to the discretion of the animal owner(s) and the receiving slaughterhouse, but must provide positive and legible identification of animals with their owner(s). For regulatory purposes, responsibility is lodged with the slaughter establishment and must be maintained until inspection is completed.

No animal could be slaughtered without positive identification and record of ownership. All official establishments, Federal and State, would be required to keep accurate records identifying all animals purchased along with the name and address of the person or persons who owned the animal over the previous 90-day period unless otherwise prescribed by regulations.

Any animals lacking positive identification would require a holding period as prescribed by regulations before it could be presented for inspection.

(e) Major expansion of residue testing activities. Discussions of the residue monitoring program often include a recommendation that, however it is phrased, really means test more animals more rapidly. The GAO report specifically recommends the strategy pursuing this end: "...that the Secretary of Agriculutre develop the capability to conduct residue analyses at the slaughterhouse and encourage the expansion of private monitoring efforts." The report of the House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations on "Cancer-Causing Chemicals in Food"

addresses the issue more generally: "USDA's 'random sample' monitoring program should test more animals for chemical residues. Testing only 1 in 8,000 livestock and 1 in 700,000 poultry does not afford a true picture of the extent and nature of chemical contaminants in meat and poultry." Both these recommendations recognize that testing every animal for chemical residues with existing methods is unrealistic. Costs are prohibitive, exceeding $50 billion for livestock alone; significant quantities of edible tissue would be removed from the food chain; processors would be obliged to expand their facilities to hold carcasses pending laboratory results. Less ambitious expansion efforts are constrained by: (1) lack of technology to rapidly test for the majority of residues (the STOP program is an exception); and (2) the lack of laboratory capacity to handle increased numbers of analyses. A major expansion strategy could include the following elements: (1) expansion of the STOP program to other species with historic patterns of violative antibiotic residue levels; (2) expansion of research and development activities to multiply by 10 efforts to produce rapid-test methods for all classes or residues; (3) expansion of laboratory facilities to accommodate sampling at 20 times the present rate using existing methodologies and procedures; (4) expansion by 5 times of private monitoring efforts.

(f) More rigorous enforcement, including the use of civil penalties. The GAO report recommends that FDA authority be amended to include provision for using civil penalties as an intermediate alternative to criminal actions (now rarely pursued by FDA) and information letters (now commonly used even when the violation is a result of deliberate misuse). There is some comparable experience which can be reviewed: the Department has a Horse Protection Program which includes assessing fines on known violators; since 1972, EPA has had authority to use civil penalties inder FIFRA.

The EPA effort is carried out through Regional Offices which have sizable legal enforcement staffs; investigative field work is carried out largely under contract to States, using approximately 10 inspectors per State. Guidance to regional legal staffs is provided through a detailed case proceedings manual, assuring some consistency in the program. The fine structure is complex and statutorily established with a maximim fine of $5,000, and requirements that the fine consider the gravity of the offense, the appropriateness of the fine to the size and character of the concern charged, and the ability of the concern to remain in operation if so fined. Approximately 80% of the cases where civil penalties are sought are settled by consent orders without the use of a formal hearing procedure.

The Horse Protection program operated by APHIS also uses civil penalties as a corrective strategy with a maximum fine of $1,000. Recent legislative amendments have added disqualification as a

possible penalty, with potential financial loss far in excess of the existing fine structure. The program is operated within tight fiscal contraints; modest numerical achievements can be attributed to limited funding. At the $300,000 annual level, approximately 200 violations are reported to APHIS by field investigators. Of these, 10 - 14% are prosecuted. This rate is limited by resources available, and approximately 90% of these are recommended for fines rather than criminal action. The majority of the civil penalty cases go to formal hearings, which require staff and witness resources.

6. USDA and Other Federal Costs

Displayed below are the options considered and the estimated Fiscal Year 1980 costs to USDA and other Federal agencies; bases for these estimates are supplied in Attachment A.

Option	FY 80 USDA/Federal Costs
(a) No program	0
(b) Status Quo	$11.8 million
(c) Quarantine Only	$15.4 - 18.1 million
(d) Quarantine & ID	$15.4 - 18.1 million
(e) Major expansion	$92.5 million
(f) Civil penalties	$17.4 million

7. Expected Impacts

(a) Impact on main purpose and need to which action is addressed. The general purpose is to reduce the amount of adulterated meat and poultry reaching the consumer. The specific objective addressed by this proposal is to increase capability to trace carcasses with violative residue levels to producers, and to strengthen measures available to correct the problem. Options considered may address the specific objectives directly or indirectly through a deterrent effect. The options are displayed below with information about their potential direct and indirect impacts on the specific objectives:

	Direct impacts on main purpose		Indirect impacts on main purpose	
n	Increase traceback	Strengthen measures to cause correction	Deterrent fear of getting caught	Deterrent education about cause of problem
o program	----	----	----	----
tatus Quo	----	----	----	----
uarantine Only	----	x	x	x
uarantine & ID	x	x	x	x
xpansion	----	----	x	x
ivil penalties (& ID)	x	x	x	----

Discussion of expected impacts for options considered. Option (a) no program: This option avoids the problem completely. Choosing this option would result in a rearrangement of Federal responsibilities for protecting the public from violative residues in meats and poultry; it could also trigger decisions to withdraw approval of some drug use is animal production. (For fuller discussion of consequences of such a decision, see Boehm report.)

The present residue monitoring program is not designed to solve the problems of chemical residues in meat and poultry. But without this program, it would be extremely difficult to determine whether problems even existed. It probably would be impossible to discover problems promptly, or to determine their extent. In the case of animal drugs, producers would have less incentive to observe withdrawal times and husbandry practices designed to minimize the chances of residue contamination.

Two of the most notable residue problems in recent years have involved diethylstilbestrol (DES) and sulfa drugs. The Food and Drug Administration recently took action to ban DES, and the Department of Agriculture has undertaken an extensive on-the-farm survey and education program to eliminate sulfa residues in pork. The residue monitoring program was responsible for gathering the data that formed the basis for concerted government action against each of these public health problems.

Option (b) status quo: This option does not bring new resources to bear on the problem; consequently, no reduction can be anticipated in the percentages of non-traceable-residue-violative carcasses or in the proportions of known violators who refuse to cooperate. There have been no impact evaluations of the current program; the GAO report judges it to be a less-than adequate part of an ineffective Federal effort. Program officials tend to be more optimistic

noting modest reductions in overall levels and looking toward reductions in some specific residue-species combinations, such as sulfas in swine and antibiotics in cull dairy cattle. The number of potentially violative carcasses which do not now reach the market because producers have identified animals and cooperated with voluntary "hold and test" provisions is not known. A method for estimating that impact with available data is discussed in Attachment B.

Option (c) quarantine: This option adds a new enforcement mechanism, the authority to know about and control the movement of animals when their producer has previously marketed residue-violative carcasses. Quarantine authority will directly affect the 45% of identifiable producers not now cooperating, and the deterrent effect of a working quarantine program can be expected to increase the overall impact significantly. It is not unreasonable to expect that this option will be twice as effective as the status quo.

Option (d) quarantine plus animal ID. Animal identification can be expected to enhance the effectiveness of a quarantine authority. Assuming a constant number of violations, options (b), (c) and (d) would have effects displayed below:

	(b)	(c)	(d)
#Violative	1000	1000	1000
#Traceable	700	700	1000
#Correcting	390	700	1000
% Improvement	----	80	128

Option (e) major program expansion. This option brings major new financial resources to bear on the problem; however, the effects on violation rates cannot be readily estimated because they occur indirectly, depending on how producers react to the vastly increased chance that residue-violative carcasses will be detected.

Option (f) civil penalties. If this option were added to the chart above, its numbers would be : 1000 violative, 700 traceable, 390 - 700 correcting, depending on the effectiveness of fines in persuading producers to change. That effectiveness is not known; caveats expressed by EPA and APHIS are worth noting: from EPA there was indication that the complex fine structure in their statute was highly protective of farmers and reduced the effect of the penalties; from APHIS the caution that civil penalties alone will not do it, especially for the repeater. Probably both comments indicate that there will never be a big enough fine to keep the persistent violator down.

(b) Cost Impacts

Producer costs associated with the various options must be reviewed with care. Options which do not include animal ID will have costs distributed among the producers to whom violative carcasses can be traced; options which do not include enforcement penalties, such as quarantine or civil penalties, will have costs distributed among those who cooperate rather than all producers. Both producers and packers would incur additional costs as a result of mandatory animal ID. Costs to the producer would consist mainly of the labor cost of affixing tags or marking animals in another fashion. Costs to the packers (and to stockyards, salebarns, and other intermediate points in the supply chain) would consist mainly of recordkeeping costs. The cost of marking animals would account for roughly one-half of the cost per head of mandatory ID, and the recordkeeping would account for the other half. Estimated producer and packer costs for each option are displayed below; methods for computing estimates are described in Attachment C.

Option	Producer Costs
(a) No program	0
(b) Status Quo	$1.5 million
(c) Quarantine Only	$4-6 million
(d) Quarantine & ID	$6-8 million
(e) Major expansion	$7 million
(f) Civil penalties	(dependent on fine structure)

Consumer costs are not expected to be significantly affected as a result of distributing among all producers the costs of producing carcasses without residue contamination. Possible disruptions in supply could occur in instances of isolated small producers and local markets.

8. Significant Social Effects

Options (c) and (d) which address the problem directly, are likely to achieve measurable reductions in the residue contaminated meat and poultry products reaching consumers. These reductions are likely to have significant public health benefits, although

the magnitude of those benefits is not now estimable. (See discussion of public health dimensions of problems, Section 3, above.)

9. Distribution of Effects

Consumer Impact - The effects of the proposal would be distributed throughout the entire population and would be limited only to the extent that meat or poultry is a part of the daily diet.

Industry Impact - The randomness of the tissue sampling process, would assure that no producer group or geographical area would be exempt from the quarantine provisions. Current producers not cooperating would be most heavily impacted, as intended. Small producers with marginal profits would be likely to feel more acutely the cost impacts of changing practices to assure safe carcasses. Those producers are also likely to benefit significantly from the educational and technical assistance elements of the program. The numbers of small producers - generally understood to be operations of less than 100 individuals - are not known. Implementing regulations can be developed to minimize the impacts on this group. For instance, animal ID responsibilities may be burdensome on small slaughtering operation used to receiving and mixing small lots. To alleviate this problem, tags and application devices normally conveyed to the farmer could be supplied to the small business.

Quarantine provisions with built-in educational technical assistance through site visits may be especially beneficial to small producers who lack detailed information on correct practices.

State Government Impact

States choosing to operate State quarantine programs would be more affected than other States by this proposal because they would be responsible for implementing the quarantine authority involving intrastate violations.

Notes

1. Carol Tucker Foreman, statement before the Subcommittee on Oversight and Investigations, Interstate and Foreign Commerce Committee, House of Representatives, February 24, 1978, pp. 1-2.

2. William T. Boehm, et.al., The Economic Effects of A Prohibition on The Use of Selected Animal Drugs, U.S. Department of Agriculture; Economics, Statistics and Cooperatives Service, September 1978, p. 11.

3. Ibid.

4. "Antibiotics and the Food You Eat", FDA Consumer Memo, HEW Publication No. (FDA) 78-6011, Revised March 1978, p. 1.

5. Boehm, et.al., p. 15.

6. H. Dwight Mercer, D.V.M., "Antimicrobial Drugs in Food-Producing Animals: Control Mechanisms of Governmental Agencies. Veterinary Clinics of North America - Vol. 5, No. 1, February 1979, p.

7. Comptroller General of the United States, "Report to the Congress: Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues", United States General Accounting Office, April 17, 1979, pp. i - ii.

8. Foreman, p. 11.

Attachment A

Basis For Estimating USDA and Other Federal Costs

1. Option (a) program: No costs incurred.

2. Option (b) status quo: $11.8 million in FY 80 budget attributable to National Residue Program costs.

3. Option (c) quarantine only: $15-17 million.

   Assume 2000-3500 quarantines per year; total number quarantines assumed is 2-3 1/2 times the 1978 number of violations, attributable to a doubling of the monitoring program and the minimum impact of first full year of STOP.

   Assume site visit costs, including personnel and materials at $750, and an average of 2 visits per quarantine. Much of the educational material is now available out of the current budget. The quarantine program would provide the opportunity to target it to producers, who would be most in need and most receptive.

   Subtotal - $3 - 5.25 million.

   Add - $11.8, anticipated FY 80 budget

   Total Approximately $15 - 17 million

4. Option (d) quarantine plus ID

   Assume costs detailed for quarantine only. Additional costs to APHIS to distribute identification devices assumed to be minimal as APHIS now does this for its animal disease programs. If any additional USDA costs incurred, it is unlikely that they would push total FY 80 costs over the range described above.

5. Option (e) major expansion: $92.5 million

   Expand STOP: no cost/major increase in analyses to be done.
   Expand R&D: 2.5 million — STOP development costs atypically low $50,000. assume $250,000 development cost per new test (10 new tests).

   Expand labs: 90 million — Assume 80 additional laboratories, placing testing capacity within 500 miles of most slaughtering operations, reducing time needed to get results. Assume 50% or annual capacity of 40 labs handled by contract operations.

Cost of new federal labs	$40,000,000
Operating costs (annual)	$10,000,000
40 lab/year private contracts	$40,000,000
1 lab/yr = 20,000 analyses	
av cost per analysis = $50	

Expand private monitoring: no new costs.

6. Option (f) Civil penalties:

Assume 2000 - 3500 violations treated with civil penalties. Use APHIS costs estimates, multiplied by a factor of 10.

Field investigative costs	$3 million
Compliance costs 52 person-years x $50,000 per	$2.6 million
FY 80 program costs	$11.8 million
	$17.4 million

Attachment B

Estimating the Number of Potentially Residue-Violative Carcasses not Reaching the Market under Current Program

The 1978 data on violations by residue/species are displayed on Table 1.

Slaughter lot sizes by species are estimated as shown on Table 2.

The portion of a slaughter lot likely to be violative is estimated as shown in Table 3; it is important to remember that these are highly conjectural figures.

Assume that the 60-80% rate of carcasses traceable to a producer and the 55% rate of cooperation with "hold and test" provisions apply uniformly to producers.

It is then possible to estimate the number of violative carcasses, the proportion traceable to producers, and the number of potentially violative animals withheld; these estimates are displayed in Table 4.

Option (b) uses 1980 projections, including a doubling of the sampling and violation rate. Using this method, # animals withheld under option (b) comes to:

	Cattle	Calves	Swine	Turkey
# Withheld	4370	3888	25154	235620

Table 1 1978 Data Monitoring Program

	Cattle	Calves	Sheep & Goats	Swine	Horses	Chickens	Turkeys	Ducks & Geese	Rabbits	Total Violations
Chlorinated Hydrocarbons	10	1	0	2	0	0	0	0	0	13
Antibiotics	46	94	5	76	5	8	15	2	32	283
DES	9	0	0	0	0	0	0	0	0	9
Sulfanomides	2	6	0	648	0	1	19	0	0	676
Total Violations	67	101	5	726	5	9	34	2	32	981
% Total Violations	7	10	.5	74	.5	1	3.5	.2	3.3	

Table 2: Slaughter Lot Size from Producer

40-300 1-5 Dairy	50-150	50	10,000-20,000	10,000	1,000-2,000	5-20	

Table 3 Portions of Herds Likely to be Violative*

Residue Class	Cattle	Calves	Sheep & Goats	Swine	Horses	Chickens	Turkeys	Ducks & Geese	Rabbits
Chlorinated Hydrocarbons	Extremely variable 10 - 100% depending on cause. Contaminated feed may result in 100% violations. Isolated environmental contamination, less than 10%.								
Antibiotics	Therapuetic practices may yield continued violations.					----------Near 100%----------			
DES	Near 100%		Near 100%						
Sulfonamides	10-100%	10-100%		100&	Individual	----------Near 100%----------			

* Tentative estimates are dependent on:
1. Source of exposure, whether uniform or isolated;
2. Depletion time and stage of depletion in relation to tolerance;
3. Practices such as addition or removal or specific animals from a herd.

TABLE 4 Estimated Numbers of Selected Species likely to tbe Violativ , not Reaching Market under Current Program

	Cattle	Calves	Swine	Turkeys
# Violative	5695	5050	32,670	306,000
# Identifiable	3972	3535	22,869	214,200
	2185	1944	12,577	117,810

Attachment C

Producer Cost Estimates

Option (c) Quarantine

Assume 2000-3500 quarantines, distributed in proportion to residue-species violations (1978 data).

1. Loss due to voluntary destruction on premises, plus animals condemned on pre-test at slaughter

Voluntary destruction usually limited to chickens and turkeys.
Assume destruction in 1% quarantines applied:

.04(2000-3500) = 80 - 140 ch/turk quarantines	
.01(80-140) = 1 flock destroyed	
av size flock 12,5000 x 1$ per =	12,500
Assume 10% pretest animals violative from red meat quarantines, animal values $100 - 700.	
.1(2500) 5 animals($400) =	500,000
	512,500

2. Loss due to delays in sale on animals-waiting for depletion of residues, waiting for pretests-reduced market values

Assume by-species costs for 2-wk holding as shown below:

Species	Mkt Val	Loss	Daily Feed Maintenance	Total
Dairy Cattle	700	250	3.00	1460
Calves	300	20	2.00	100
Hogs	100	10¢/lb if near 300	1.00	140
Chickens			$100/1000	2000
Turkeys				20,000

1. Dairy cows x 200 cases	292,000
2. Calves x 300 cases	30,000
3. Hogs x 2000 cases	280,000
4. Chickens x 20 cases	40,000
5. Turkeys x 60 cases	1,200,000
	1,842,000

Attachment C (cont'd)

3. Loss due to cleaning requirements

Highly variable, costs ranging from $50 - 500
For 2000 violations $100,000 - 1,000,000

4. Cost of testing at producer expense $1,500,000

Total quarantine $4,404,500.

Option (d) quarantine and ID

1. Costs for individual animal ID

Cattle: tag and identification device furnished by APHIS; cost to producer and packers to apply and to keep records 10¢/head
.10(20% of 36 million head) = $720,000

Hogs: tags and application devices supplied; costs to producer to apply and keep records 5¢/head
.05(40% of 74 million head) = $1.5 million

2. Animals more readily identified by lot will result in record-keeping costs for producers, and some additional identification costs to slaughterers and packers not holding lots separately

Estimate .5 million

Total producer costs of animal identification $2.7 million

Option (b) Status quo

Assume 2000-3500 FY 80 violations
identifiable 1400 - 2450
cooperating 770 - 1350

Assume 78 residue-species distribution

Species	%violations	#cases
Dairy cows	7	74
Calves	10	106
Swine	74	784
Turkeys	4	42

1. Loss due to delays

Dairy cows	1460(75)	108040	
Calves	100(106)	10600	
Swine	140(784)	109760	
Turkeys	20000(40)	800000	
	1004	1028400	$1,028,400

Attachment C (contd)

2. Cleaning costs			
1004 violations($50 - 500)		$50,000 - $500,000	
Total, Option (b)	1,303,400		$275,000

Option (e) Major Expansion

1. Costs to identifiable cooperating producers

Assume identification and cooperation rate constant.
@ .70 and .55, sample
size 10 x that of option (c)
cases voluntary cooperation = 7700,
Approximately 3 x number cases.
in option (c) cost estimate

3(512,500 x 1,842,000) = $7,063,500

NOTES

NOTES

1. Clement Associates, Inc., Washington, D.C., "Priority Setting of Toxic Substances for Guiding Monitoring Programs."

2. The Federal Regulatory Council was created by President Carter in October 1979 to improve the process of government regulation. The Council has representatives from 35 different agencies.

3. The Toxic Substances Strategy Committee (TSSC) was established by the President in his 1977 Environmental Message.

   The committee is chaired by the Chairman of the Council on Environmental Quality (in the Executive Office of the President), and includes 17 agencies involved in the effort to control toxic substances. Assistant Secretary Foreman is a member representing FSQS. TSSC was established (1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) to coordinate Federal research and regulatory programs affecting them.

4. Report to the President by the Toxic Substances Strategy Committee, Council on Environmental Quality, Public Review Draft, CEQ-EHTS-03, August 1979.

5. The Interagency Regulatory Liaison Group (IRGL) was formed in 1977 by four agencies--the Consumer Product Safety Commission, the Occupational Safety and Health Administration, and was expanded in December 1978 to include the Food Safety and Quality Service of the Department of Agriculture.

The purpose of the IRLG is to improve the public health through sharing of information, avoiding duplication of effort, and developing consistent regulatory policy.

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

JAN 17 1980

Honorable Robert Eckhardt
Chairman, Subcommittee on Oversight
and Investigations
Interstate and Foreign Commerce Committee
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am transmitting to the Subcommittee the attached report on last years' polychlorinated biphenyl (PCB) contamination in the Western United States.

The report began as a followup to my September 28 testimony before your Subcommittee. It is intended to provide further information on many of the questions that were left unanswered at the time of the hearing, and I think it fulfills this purpose. It provides a full and accurate account of the discovery of the contamination and the Agency's actions in response to it.

The report, however, has grown in scope well beyond its original purpose. We have attempted to use the review of this incident as the occasion for an intensive examination of our residue program and an evaluation of our ability to respond to incidents such as the recent PCB contamination. As a result of this self-examination, I believe we now have much better knowledge of our limitations as well as the possibilities for providing better protection for American consumers.

Some limitations are the inevitable result of the present lack of adequate technology. For example, there are still no suitable tests for detection of many toxic chemicals that may occur in the food supply. Many of the tests we do have depend upon complicated and expensive analytical techniques which limit coverage and create time-lags in detection. For this type of limitation, there is no immediate solution beyond the continued research in which the Department is now engaged.

Other limitations, however, can be overcome. We have already taken a number of corrective actions, and further actions are planned in the months ahead. We have been able to use the lessons gleaned from the recent incident to tighten considerably our procedures for responding to environmental contamination. We have defined the conditions that will trigger a coordinated response and have established distinct channels of communication, explicit responsibilities, and a set of contingency plans that will enable us to respond in a more expeditious fashion in the future. These steps are described in some detail in Section IV of the report. In addition,

we will be issuing new regulations within the next several months that will lead to the phase-out of PCBs in meat, poultry, and egg product plants, and will be submitting a legislative proposal to Congress that would close off gaps in our present authority to deal with residue problems.

Even considering technological limitations, it appears that our residue monitoring can and should be redesigned to provide better coverage (that is, great likelihood that contamination incidents will be detected). The present monitoring effort provides 95 percent assurance that over the course of a year it will catch any contamination that involves more than one percent of the Nation's meat and poultry supply. As I pointed out in my September testimony, it was purely by chance that we detected the most recent PCB contamination. The Agency is now reexamining the statistical basis of the present program to see how the net might be tightened. We are studying the use of increased sampling, earlier sampling, reliance on private monitoring programs, and a broadened information base. Over the next few months, we will be moving the national monitoring program in new directions that will provide increased protection for consumers.

There are two further matters directly connected with the PCB incident that will be resolved in the near future. First, the Agency will be deciding whether any disciplinary action against individual employees is warranted. Second, the epidemiological review of producers and the stepped up PCB monitoring program still continue in the States of Montana and South Dakota. This effort has encountered no major problems, and we expect the final clean-up phase to be completed by July of this year.

I appreciate the continuing interest of the Subcommittee in this matter, and will keep you informed as we make progress in this important area.

Sincerely,

Carol Tucker Foreman

CAROL TUCKER FOREMAN
Assistant Secretary for
Food and Consumer Services

Enclosure

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